ENHANCED RECOVERY PROTOCOL FOR SUBTOTAL GASTRECTOMY

A dissertation submitted to the M.G.R. Medical University, Tamil Nadu in partial fulfillment of the requirement for the M.S. Branch I (General Surgery) examination held in April 2016.

Contents

DEPARTMENT OF GENERAL

SURGERY

Christian Medical College, Vellore

Certificate

This is to certify that the dissertation titled ***'Enhanced recovery protocol for subtotal gastrectomy -*** A prospective cohort to assess whether post-operative recovery following subtotal gastrectomy can be enhanced by following a structured protocol.*'* is a bonafide work by Dr. Nandu Nair, submitted in partial fulfilment of the rules and regulations for the M.S (Branch I), General surgery examination of the Tamil Nadu Dr. MGR Medical University, to be held in April 2016

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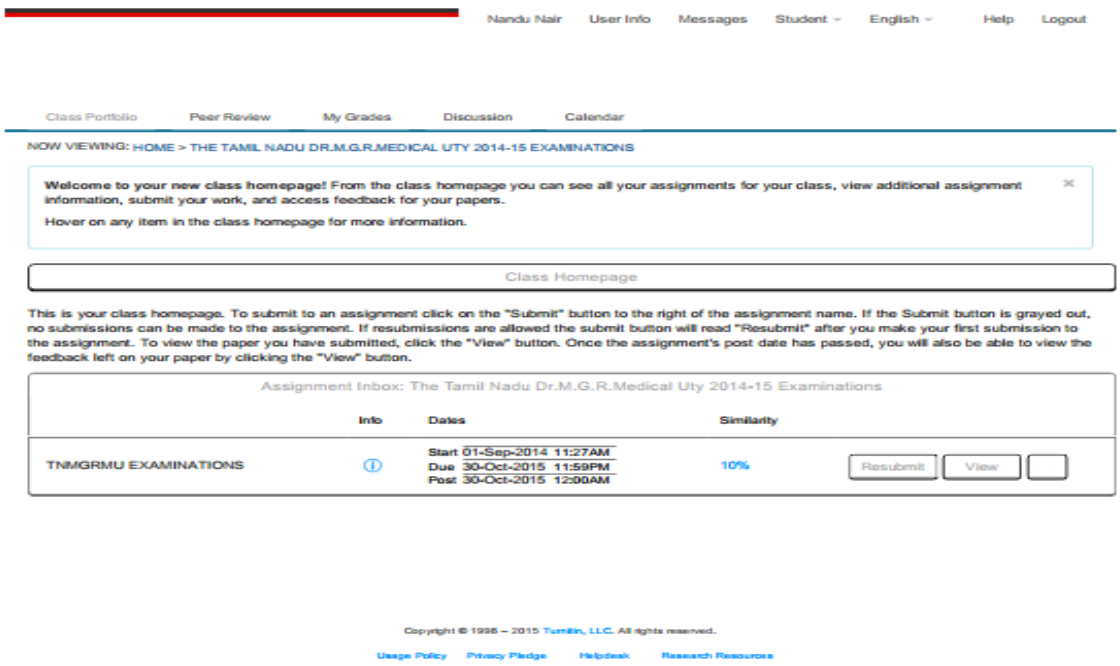

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ABSTRACT

BACKGROUND

The concept of Enhanced Recovery After Surgery (ERAS) or Fast Track Protocol was pioneered by Bardram. Later popularised by Kehlet and Wilmore. ERAS consists of a protocol of interventions aimed at stimulating early recovery following surgery and reducing the stress response to surgery thereby reducing the morbidity following a major procedure. It was initially tried for elective colorectal surgeries. Due the promising results, this protocol has been tried in cardiovascular surgeries, urological procedures (radical cystectomy, nephrectomy) and is being tried in other specialities as well. Recently some studies have been done on the effectiveness of ERAS protocol in upper GI procedures. Although most of these studies show promising results by reduction in the duration of post-operative hospital stay and also a reduction in postoperative complications, some studies show no particular benefit. There is no consensus guideline for ERAS in upper GI surgery. Hence more studies and meta-analysis is required before the effectiveness can be conclusively proven. Also, no studies have been done to find out effectiveness of ERAS protocol among Indian population.

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ABSTRACT

BACKGROUND

The concept of Enhanced Recovery After Surgery (ERAS) or Fast Track Protocol was pioneered by Bardram. Later popularised by Kehlet and Wilmore, ERAS consists of a protocol of interventions aimed at stimulating early recovery following surgery and reducing the stress response to surgery thereby reducing the morbidity following a major procedure. It was initially tried for elective colorectal surgeries. Due the promising results, this protocol has been tried in cardiovascular surgeries, urological procedures (radical cystectomy, nephrectomy) and is being tried in other specialties as well. Recently some studies have been done on the effectiveness of ERAS protocol in upper GI procedures. Although most of these studies show promising results by reduction in the duration of post-operative hospital stay and also a reduction in postoperative complications, some studies show no particular benefit. There is no consensus guideline for ERAS in upper GI surgery. Hence more studies and meta-analysis is required before the effectiveness can be conclusively proven. Also, no studies have been done to find out effectiveness of ERAS protocol among Indian population.

AIM

To study effectiveness and feasibility of ERAS protocol in patients undergoing subtotal gastrectomy for carcinoma stomach in Surgery III unit, Christian Medical College, Vellore.

OBJECTIVES

- To study whether ERAS protocol reduces the duration of post-operative hospital stay in patients undergoing subtotal gastrectomy in CMC during the period of November 2013 to July 2015
- To study the effect of ERAS on morbidity following subtotal gastrectomy.
- To study the compliance of study population to ERAS protocol.

METHODOLOGY

This study was a prospective observational cohort study includingadult patients with a confirmed tissue diagnosis of adenocarcinoma stomach, who underwentelective subtotal gastrectomy in the Surgery III unit at CMC hospital. All patients registered for the study followed the modified ERAS protocol

which consisted of preoperative, intraoperative and postoperative interventions (Table 1). Patients and their caregivers were counselled about the components of the protocol and given a printed hand-out regarding the protocol. They were followed up daily after operation to record adherence to protocol. If any intervention in the protocol is not followed the reason for the same was recorded. These patients were discharged when they satisfied the predetermined criteria for discharge. These patients were kept under regular follow up for a period of one month to watch for any postoperative complications. Primary outcome wasduration of hospital stay and secondary outcomes studied included protocol compliance, postoperative complications (as per Clavien Dindo classification), day of passage of flatus and faeces following surgery, day of initiation of normal diet and any need for readmission.

RESULTS

44 patients were included in the ERAS group and were compared with historical controls. The median duration of hospital stay was less in patients following the ERAS protocol (6 days) as compared to the historical control group who received conventional postoperative care (7 days) however the

difference was not statistically significant. Among the components of modified ERAS protocol used, early nasogastric tube removal was the intervention which had least adherence due to surgeon preference. ERAS following subtotal gastrectomy was not associated with any increase in rate of immediate postoperative complications or any increase in morbidity.

INTRODUCTION

Enhanced Recovery After Surgery (ERAS) also known as Fast Track Surgery (FTS) or critical pathway (CP) consists of multiple evidence based protocols which when followed has proven to reduce the stress response to surgery thereby improving the outcome of the procedure and expediting recovery. Initially popularised for colonic procedures, this concept has now been successfully explored for other major procedures in other branches of surgery as well. Few studies have been done to develop similar protocol for upper gastrointestinal procedures including gastrectomy with varying results. Effectiveness of such a protocol has not been studied on the Indian population. This study was aimed to assess the effectiveness of ERAS protocol among people undergoing subtotal gastrectomy for carcinoma stomach in Christian Medical College, Vellore. Surgery being the mainstay and only curative option for carcinoma stomach, this study aims to assess whether following a structured ERAS protocol can reduce the duration of hospital stay among patients undergoing subtotal gastrectomy and to compare the immediate postoperative morbidity among these patients thereby reducing the cost of treatment and early return to normal activity.

AIMS AND OBJECTIVES

AIM

To study the feasibility and effectiveness of an enhanced recovery (ERAS) protocol in patients with carcinoma stomach undergoing subtotal gastrectomy in Christian Medical College (CMC), Vellore during November 2013 to June 2015.

OBJECTIVES

1. To study whether ERAS protocol reduces the duration of post-operative hospital stay in patients undergoing subtotal gastrectomy in surgery 3 unit, CMC hospital during the period of November 2013 to July 2015.

2. To study the effect of ERAS on postoperative complications following subtotal gastrectomy.

3. To study the compliance of ERAS protocol among study population.

LITERATURE REVIEW

Cancer is a major public health problem in most parts of the world and has been attributed to one in four deaths in the United States of America(1). Cancer of the stomach contributes a major share of cancer morbidity and mortality and affected 6.8% of world population in 2012 alone(2). Stomach cancer is currently the fourth most common cancer and is the second most common cause of cancer deaths worldwide(3).

GLOBAL EPIDEMIOLOGY OF STOMACH CANCER

Stomach cancer was the leading cause of cancer deaths worldwide till the 1980s and is currently second to lung cancer. Incidence and mortality of stomach cancer has been decreasing over the last two decades which has been attributed to various reasons(4,5)(6,7). There is also a significant difference in the incidence based on geographical variation. Highest rates of incidence are in Eastern Asia, Eastern Europe and South America as compared to low rates in North America and most parts of Africa(8).The developing countries bear over 70% of the stomach cancer burden, especially Japan and China .The age adjusted incidence rates in 2014 were highest in Asia(9). Another study showed incidence rates(per I lakh) ranging from 3.3 and 2.0 in men and women

respectively in Egypt to 65.9 and 25.9 in men and women in Korea(10). However there have also been reports of increase in incidence of oesophageal and gastric cardia malignancies which has been partly attributed to increasing gastroesophageal reflux disease as part of obesity and to smoking(11,12).

STOMACH CANCER IN INDIA

Stomach cancer is one of the leading cause of cancer related deaths in India. In a survey by Dikshit et al,Gastric cancer was found to be amongst the three most common fatal cancers in India in the age group of 30 to 69 years(13). Although the incidence of carcinoma stomach in India is less certain geographic areas like southern and north eastern India have incidence comparable to other high incidence regions of the world(14).According to the national cancer registry,the maximum incidence is in Aizwal in Mizoram(15). Number of new cases of carcinoma detected per year in India accounts to 34000 with a male predominance of 2:1 and it is estimated that by the year 2020 approximately 50000 new cases of stomach cancer will be detected per year(13).

ETIOLOGY OF CARCINOMA STOMACH

There is a significant geographic and ethnic variation in the incidence of carcinoma stomach. There was also a significant variation in the incidence of cancer among immigrants based on where they lived. These findings strongly suggested modifiable risk factors like diet to be associated with causation of carcinoma stomach(16). Processed meat and nitroso compounds are associated with an increase in the gastric cancer risk(16) and so are salts and salted foods(17). Fruits, vegetables(16,18), lycopene, lycopene-containing foods(19), vitamin C, Selenium, legumes, black tea and pulses were found to be protective(19). Pickling and salt-preservation of foods increases the cancer risk(17).

Helicobacter Pylori prevalence closely parallels the cancer incidence and lots of research has been published regarding its effect on gastric cancer after its first description by Marshal in 1983(20). It is implicated in intestinal metaplasia, atrophic gastritis and gastric carcinoma(21), Correa P et all proposed that infection with H Pylori initiates a cascade of events including the release of oxygen free radicals from the inflammatory cells,leading to carcinogenesis(22). In a meta-analysis by Fuccio L et al the eradication of H

Pylori was shown to reduce the gastric cancer risk(23). Similar results were obtained in studies conducted by Wu CY et al(24) and several others(25–30).

There is also a possible association between previous gastric surgery and gastric cancer which was first noted in 1922 and that the risk was significant after 15 years of surgery(31). Strongest association has been found following gastrectomy for peptic ulcer disease followed by vagotomy or surgery for duodenal ulcer(32–35).

Ionizing radiations have also been postulated as a causative factor for carcinoma stomach. Studies in survivors of the atomic bombings and other cohort studies in patients who received radiation for peptic ulcer disease and testicular tumours indicate a two to four fold increase in incidence of stomach cancers(36–39).

Hsing et al. observed association between pernicious anaemia and stomach cancer with up to three fold risk(40).

Smoking has been reported to have mild to moderate risk but studies have not found association between alcohol consumption and stomach cancer(41–48).

PATHOLOGY

Majority of gastric carcinomas are adenocarcinoma (90%). Non Hodgkins lymphomas and leiomyosarcomas constitute majority of the remaining 10%(49). Other types of cancers include Adenosquamous, squamous, and undifferentiated carcinomas. Choriocarcinomas, carcinoid tumors, rhabdomyosarcomas, and hemangiopericytomas are the other very rare malignant primary tumours.

Adenocarcinomas have been classified into intestinal type and diffuse type by Lauren in 1965(50). Another classification system used is the WHO classification system(51).

Table – 1 Lauren and WHO classification of gastric cancer

Laurén classification	**World Health Organization classification**
Intestinal type	Papillary adenocarcinoma
	Tubular adenocarcinoma
	Mucinous adenocarcinoma
Diffuse type	Signet-ring cell carcinoma and other poorly cohesive carcinomas

Indeterminate type	Mixed carcinoma
	Adenosquamous Carcinoma
	Squamous cell carcinoma
	Hepatoid adenocarcinoma
	Carcinoma with lymphoid stroma
	Choriocarcinoma
	Carcinosarcoma
	Parietal cell carcinoma
	Malignant rhabdoid tumor
	Mucoepidermoid carcinoma
	Paneth cell carcinoma
	Undifferentiated carcinoma
	Mixed adeno-neuroendocrine carcinoma
	Endodermal sinus tumor
	Embryonal carcinoma
	Pure gastric yolk sac tumor
	Oncocytic adenocarcinoma

STAGING

Most commonly used staging system for carcinoma stomach was developed jointly by the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC) (edited in 2010)(52). Another staging system is the Japanese system of classification which is more elaborate in terms of anatomical location and lymph node stations(53).

Table 2 – TNM Staging of carcinoma stomach

Primary tumor (T)	
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma in situ: intraepithelial tumor without invasion of the lamina propria
T1	Tumor invades lamina propria, muscularis mucosae, or submucosa
T1a	Tumor invades lamina propria or muscularis mucosae
T1b	Tumor invades submucosa
T2	Tumor invades muscularis propria

T3	Tumor penetrates subserosal connective tissue without invasion of visceral peritoneum or adjacent structures
T4	Tumor invades serosa (visceral peritoneum) or adjacent structures
T4a	Tumor invades serosa (visceral peritoneum)
T4b	Tumor invades adjacent structures
Regional lymph nodes (N)	
NX	Regional lymph node(s) cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in 1-2 regional lymph nodes
N2	Metastasis in 3-6 regional lymph nodes
N3	Metastasis in seven or more regional lymph nodes
N3a	Metastasis in 7-15 regional lymph

	nodes		
N3b	Metastasis in 16 or more regional lymph nodes		
Distant metastasis (M)			
M0	No distant metastasis		
M1	Distant metastasis		
Anatomic stage/prognostic groups			
Stage 0	Tis	N0	M0
Stage IA	T1	N0	M0
Stage IB	T2	N0	M0
	T1	N1	M0
Stage IIA	T3	N0	M0
	T2	N1	M0
	T1	N2	M0
Stage IIB	T4a	N0	M0
	T3	N1	M0
	T2	N2	M0
	T1	N3	M0
Stage IIIA	T4a	N1	M0
	T3	N2	M0

	T2	N3	M0
Stage IIIB	T4b	N0	M0
	T4b	N1	M0
	T4a	N2	M0
	T3	N3	M0
Stage IIIC	T4b	N2	M0
	T4b	N3	M0
	T4a	N3	M0
Stage IV	Any T	Any N	M1
Stage IV	Any T	Any N	M1

TREATMENT OF CARINOMA STOMACH

Although new modalities of treatment are under research, resection offers the best chance of survival for patients with carcinoma stomach(54,55). Surgeries for cancer stomach includes total and partial gastrectomy although for early gastric cancers endoscopic treatment is an option(56–58). Decision for type of surgery is made based on the location of cancer where total gastrectomy is usually required for tumours involving the upper one third of

the stomach(59–63). Japanese classification defines the levels of lymph nodes and has been classified to levels based on the stations of lymph nodes which have resected(64).

Table 3 – Japanese classification of lymph node stations

Lymph node stations	Site of node
No. 1	Right paracardial LN
No. 2	Lest paracardial LN
No. 3a	LN along the left gastric vessels
No. 3b	LN along the right gastric vessels
No. 4sa	LN along the short gastric vessels
No. 4sb	LN along the left gastroepiploic vessels
No. 4d	LN along the right gastroepiploic vessels
No. 5	Suprapyloric LN
No. 6	Infrapyloric LN
No. 7	LN along the left gastric artery
No. 8a	LN along the common hepatic artery (anterosuperior group)
No. 8b	LN along the common hepatic artery (posterior group)

No. 9	LN along the celiac artery
No. 10	LN at the splenic hilum
No. 11p	LN along the proximal splenic artery
No. 11d	LN along the distal splenic artery
No. 12a	LN in the hepatoduodenal ligament (along the hepatic artery)
No. 12b	LN in the hepatoduodenal ligament (along the bile duct)
No. 12p	LN in the hepatoduodenal ligament (behind the portal vain)
No. 13	LN on the posterior surface of the pancreatic head
No. 14v	LN along the superior mesenteric vein
No. 14a	LN along the superior mesenteric artery
No. 15	LN along the middle colic vessels
No. 16a1	LN in the aortic hiatus
No. 16a2	LN around the abdominal aorta (from the upper margin of the celiac trunk to the lower margin of the left renal vein)
No. 16b1	LN around the abdominal aorta (from the lower margin of the left renal vein to the upper margin of the inferior mesenteric artery)

No. 16b2	LN around the abdominal aorta (from the upper margin of the inferior mesenteric artery to the aortic bifurcation)
No. 17	LN on the anterior surface of the pancreas head
No. 18	LN along the inferior margin on the pancreas
No. 19	Infradiaphragmatic LN
No. 20	LN in the esophageal hiatus of the diaphragm
No. 110	Paraesophageal LN in the lower thorax
No. 111	Supradiaphragmatic LN
No. 112	Posterior mediastinal LN

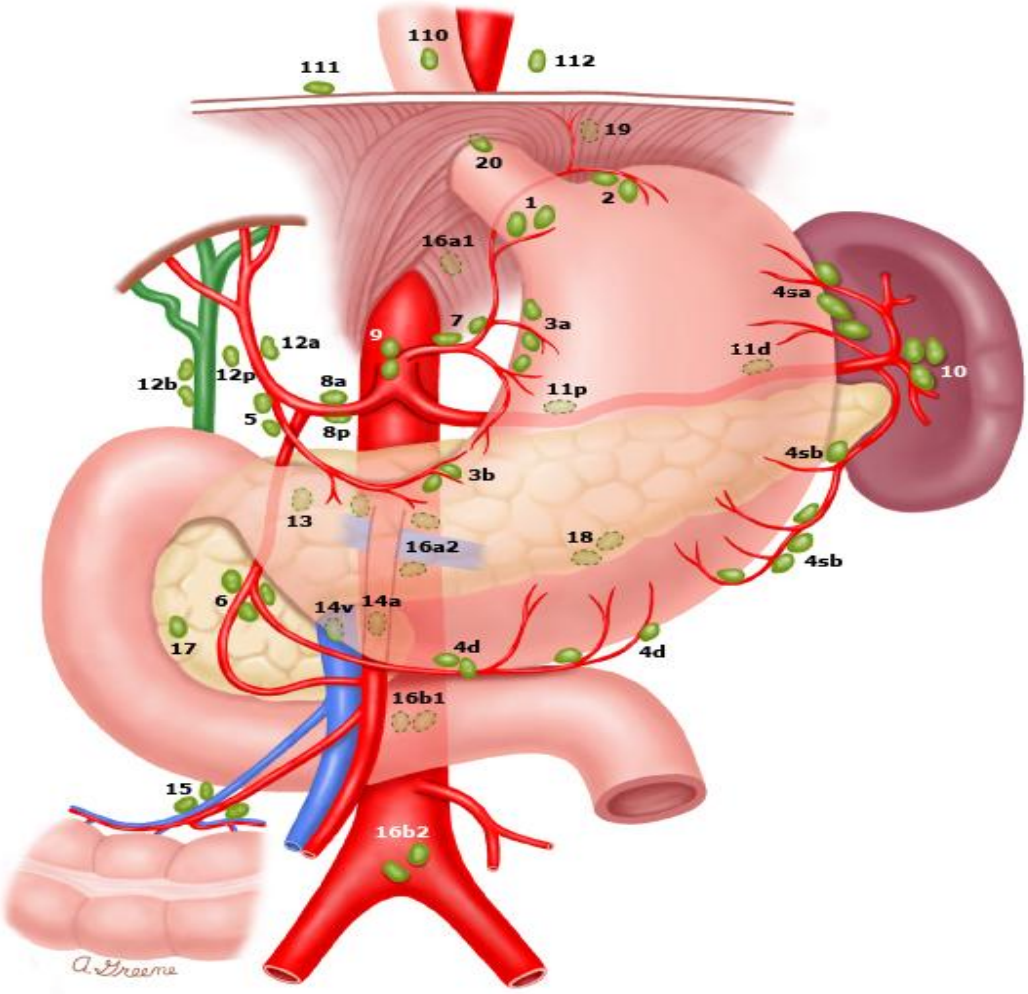


Figure 1 – Lymph nodal stations

As per the Japanese classification, all gastrectomies done in our centre were either D1 plus (including stations – 1, 3, 4sb, 4d, 5, 6, 7, 8 and 9) or D2 gastrectomies (includes 11p and 12a also). Nodal stations removed in these surgeries are mentioned in the following figure 2(65).

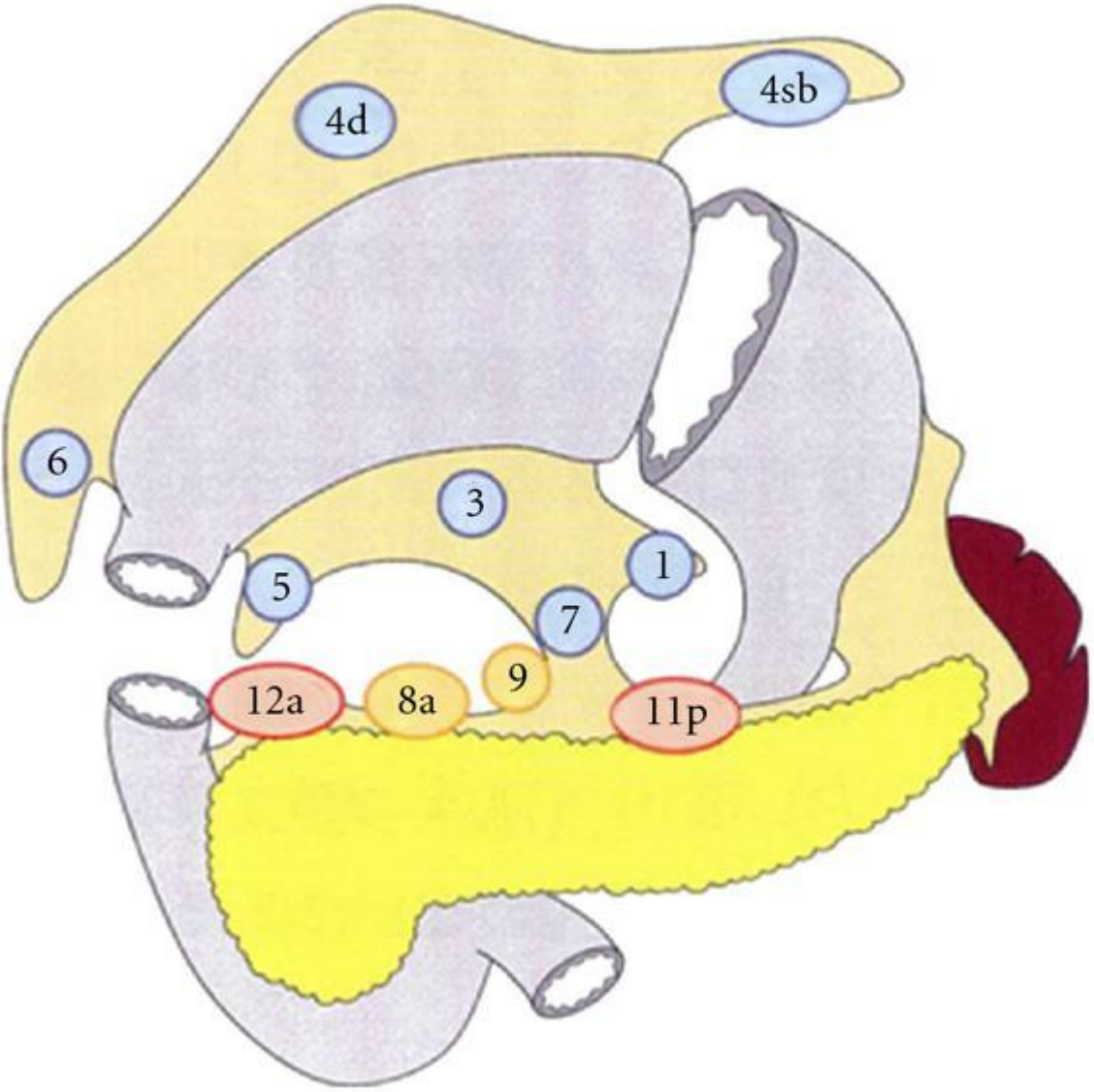


Figure 2 – Lymph node stations removed in D1(blue), D1 plus(yellow) and D2(red) Gastrectomy

POST GASTRECTOMY COMPLICATIONS

Complications following partial gastrectomy may be anatomic, related to the extent of surgical resection, physiological, due to the loss of function of the

resected segment or due to the type of reconstructive method used. Early postoperative complications include bleeding from the anastomotic site, anastomotic leak and duodenum stump blowout. Delayed complications include post gastrectomy syndromes like early and late dumping syndrome, early satiety, gastroparesis, roux stasis. Other possibilities are recurrent malignancy, late anastomotic stricture, gastro jejunal intussusception, vitamin or mineral deficiencies due to malabsorption.

ENHANCED RECOVERY AFTER SURGERY

The concept of Enhanced Recovery After Surgery (ERAS) also known as Fast Track Surgery (FTS) or critical pathway was a concept concieved by Bradram et al in 1995 in patients undergoing colonic surgery(66). It was also popularised by articles published by Kehlet and Whilmore(67,68). ERAS consists of evidence based protocols which are designed in order to standardize treatment and improve outcome by reducing the stress of surgery on the patient. ERAS is designed to simulate normal physiological response and reduce the adverse response to the stress of surgery thereby expedite recovery. It is a multimodal pathway consisting of

- Preoperative strategies
- Intraoperative strategies
- Postoperative strategies

The basis of ERAS lies behind the principle that surgery is a stress response to which body responds by releasing inflammatory mediators to cope with the stress. This stress response usually causes more harm by hampering the physiological response to healing. ERAS protocols are designed to minimize

the stress response by mimicking the normal physiological process as much as possible like reducing the period of preoperative fasting, reducing the anxiety by preoperative counselling and early return of enteral nutrition.

The concept of ERAS began by the observation by Bardram that post-operative complications can be reduced and recovery can be enhanced by reducing the stress response of surgery. Bradram in 1995, reported reduction in postoperative stay from 8-10 days to 5 days following elective colonic surgery with a combination of early enteral feeding and mobilisation, epidural analgesia and minimally invasive surgery to reduce the postoperative ileus. In his study consecutive 9 patients underwent elective colonic resection for malignancy. All surgeries were laparoscopy assisted and they received thoracic epidural analgesia postoperatively. All these patients were started on normal diet on the day of surgery. There was no increase in postoperative complications in these patients. Subsequently other studies reported similar advantage with regional anaesthesia, avoidance of drainage tubes, early catheter removal and a definitive consensus for fast track surgery was formulated in 2009(76). Multiple studies followed including many randomised control trials which showed the advantage of ERAS in colorectal surgery(69,70).

ERAS protocol has been tried successfully in orthopaedic procedures (71), Husted et al from Denmark reported a reduction in hospital stay in Denmark (11 days to 4 days) following standard procedures like total hip and knee replacements. Same protocol was also tried in various urological procedures(72,73). Mukhtar et al reported successful implementation of critical pathway protocol in patients undergoing radical cystectomy for carcinoma bladder thereby reducing hospital stay from 11.5 to 10.4 days. There was no increase in complications.Chugthai et al published an advantage in postoperative stay for patients undergoing nephrectomy when ERAS protocol was followed. Various gynaecological procedures like hysterectomy have also been found to be benefited after implementation.(74,75).

In 2009, Lassen et al reviewed the articles published till then on ERAS pathway following colorectal procedure and proposed a 20 point consensus guideline for ERAS in colorectal procedures,

1. Counselling and information

Patients should be explained about the procedure, post-operative careand pain relief. Adherence to the protocol can be ensured only if the patient has been explained about the targets for postoperative food intake and ambulation(77).

2. Preoperative bowel preparation

For colonic procedures, routine mechanical bowel preparation was not found to be useful in many randomised control trials moreover few studies moreover few studies had even found out that preoperative bowel preparation led to increased risk of anastomotic leak and a higher morbidity and mortality(78). It was also suggested that bowel preparation prolonged postoperative ileus(79).

3. Carbohydrate loading and preoperative fasting

Cochrane review of 22 RCTs has proven that fasting status of 2 hours for clear liquids and 6 hours for solid food does not increase any morbidity(80). This is based on normal gastric emptying time. However in diabetics there is delayed gastric emptying due to neuropathy.

There have also been studies which have proven better outcome and reduced postoperative complications if a patient undergoes surgery in a carbohydrate fed state. This is achieved by giving the patient clear carbohydrate rich drink 2-3 hours before surgery. This has proven to have a positive effect on postoperative insulin resistance as well as nitrogen losses and lean body mass postoperatively(81).

4. Pre anaesthetic drugs

Long acting opioids or sedatives when given as premedication for procedure has been proven to prolong postoperative hospital stay by hampering the oral intake after recovery from surgery. Short acing

anxiolytics were recommended as premedication instead of long acting medications.

5. Thromboprophylaxis

Both unfractionated heparin and low molecular weight heparin have been proven to be effective in preventing thromboembolic phenomenon and have been proven to be safe even when used along with epidural analgesia and the risk of haematoma is not increased.

6. Antibiotic prophylaxis

The guidelines for colorectal surgery advocates the use of gram positive antibiotic (preferably second generation cephalosporin) along with metronidazole as prophylactic antibiotic one hour prior to the incision. Antibiotic dose is advised to be repeated in case the surgery is prolonged for more than 3 hours.

7. Anaesthesia Protocol

Preferable use of short acting anaesthetic agents. Mid thoracic epidural analgesia which blocks sympathetic outflow along with analgesia without causing gut paralysis. Epidural anaesthesia during the surgery prevents postoperative insulin resistance and attenuates the stress response.

8. Preventing Hypothermia

Various randomised controlled trials have proven that prevention of hypothermia reduces bleeding and complications, perioperative cardiac complications and wound infections(82,83).

9. Intraoperative fluid management

According to conventional management, patients received fluids intraoperatively much more than their losses ultimately resulting in fluid

overload and causing increased complications including anastomotic complication and wound infections and resulting in prolonged hospital stay. Restricted fluid therapy and goal directed fluid therapy along with intraoperative monitoring of cardiac output has been proven to have less postoperative complications(84).

10. Minimally invasive surgery

Recent meta-analysis has confirmed that minimally invasive laparoscopic assisted procedures have earlier recovery in terms of return of function of the bowel as well as considering duration of hospital stay. A study by King et al studied the effect of laparoscopic versus open surgery in the setting of ERAS for colonic surgeries and found that there was no statistically significant improvement in duration of hospital stay(85) however more studies are awaited in this regard.

11. Prevention of postoperative vomiting

Factors which are associated with increased risk of postoperative nausea and vomiting include female gender, postoperative opioids, past history of motion sickness and non-smoking individuals. Patients with two of these risk factors have been found to have increased risk of postoperative vomiting and it has been proven to be beneficial in these patients to give dexamethasone during induction and to continue serotonin inhibitors during the postoperative period(86).

12. Role of nasogastric tube

It is proven that prophylactic nasogastric tube insertion during abdominal surgeries has no advantage especially in colonic surgeries(87). Return of gastrointestinal function has also been found to be early in patients whom nasogastric tube was avoided. Moreover it has also been proven that nasogastric tube increases the chance of aspiration during the procedure.

13. Use of intraabdominal drains

A meta-analysis by Karliczek et al proved that prophylactic drain placement did not reduce the incidence or severity of anastomotic leaks following colonic anastomosis. Thus in the protocol for ERAS, consensus is to avoid drains unless there isspecific indication.

14. Urinary catheter

Early removal of urinary catheter is advocated in order to prevent urinary tract infections and to facilitate early ambulation.

15. Postoperative analgesia and prevention of ileus

These form the main stay of ERAS protocol. Mid thoracic epidural is ideal as it provides adequate pain relief for 2 - 3 days and prevents ileus as compared to opioids. Adequate pain relief is essential for ambulation of the patient and for prevention of postoperative lung

complications. Nonsteroidal anti-inflammatory agents are preferred for top up analgesia as compared to opioids.Epidural analgesia attenuates the sympathetic stress response to the surgery without affecting bowel motility. Multiple studies have retained epidural analgesia for different durations and removal of epidural has to be timed with the dose of anticoagulant with a gap of at least 6 hours in order to prevent haematoma.

16. Postoperative nutrition

There is strong evidence to prove that, early enteral nutrition when compared to keeping the patient nil per oral for prolonged duration has better outcome in terms of reduced complication and reduced duration of hospital stay. There is also evidence to prove that in patients started on early enteral nutrition, nitrogen balance is more maintained and chances of postoperative insulin resistance is also less.

17. Early ambulation

Early ambulation is of prime importance in preventing muscle loss, improving oxygenation and preventing thromboembolism. Early ambulation can be facilitated by early removal or avoidance of drains and urinary catheter and adequate pain relief.

ERAS IN GASTRECTOMIES

As ERAS was successful in colorectal surgeries,there have been studies which have tried to incorporate the same principles to gastric surgeries.Suehiro et al in 2004 published regarding advantages of early enteral feeding. The study proved that initiation of enteral diet within 48 hours of gastrectomy was safe and that the postoperative stay was shorter with return of bowel functions earlier in this group(88).Two similar randomised control studies proved that nasogastric compression was not beneficial after surgeries for cancer stomach. Time to passage of flatus and faeces and duration of postoperative hospital stay was significantly more in patients who had nasogastric tube. Also 72 percentage of patients had discomfort due to the tube(89,90). A study by Alvarez et al showed that drains after surgery on stomach was not required. These studies paved the way towards trial of ERAS in gastrectomies.

Wang et al in 2010 and similar study by Tang et al reported accelerated recovery and shortened hospital stay in patients following fast track protocol after gastrectomy. Another study by Yamada et al also concluded that ERAS protocol was useful in patients undergoing gastrectomy(91–98).As there was

no standard recommendation for ERAS protocol in gastrectomy, these studies adapted the guidelines from colorectal surgery and modified it to suit upper gastrointestinal surgery. These studies had variations in the protocol followed and guidelines for fasting and carbohydrate feeds till 2 hours prior to surgery were not followed for gastrectomy. Few studies during this period did not show any particular benefit after application of enhanced recovery protocol(99). A study by Jeong et al reported no benefit in duration of hospital stay or cost when critical pathway was followed for patients undergoing gastrectomy(100) however majority of studies performed later on proved that ERAS protocol reduced the postoperative complications as well as duration of hospital stay.

Although there have been a few randomised controlled trials there are only two recently published meta-analysis available regarding FTS in gastric surgery. A recent meta-analysis by Chen et al which compared multiple studies published regarding ERAS in gastrectomy and reported that the postoperative hospital stay was significantly shorter in ERAS group compared to the conventional group(101). Considering the lack of standard guideline for ERAS and considering the reason that all studies published till now had based their protocol on modification of the guidelines for colorectal surgery, studies which

followed at least 7 out of the 20 guidelines mentioned in the 2009 consensus were included in the ERAS group(102). In the study, 7 RCTs were included with a total of 524 patients. There was a wide variation in the protocols followed with one RCT following epidural for analgesia and two studies used local infiltration as mode of pain relief. However all studies avoided long acting opioids as a method of analgesia. Two among the seven studies were for laparoscopic gastrectomies and the remaining were for open procedures. Analysis showed that there was significant reduction in the postoperative hospital stay (reduction by 2.6 days) in the FTS group also there was a significant reduction in expenditure. Postoperative morbidity and readmission rates were comparable among the groups. Chen et al however reported that FTS should be selectively used in patients as most of the published studies had excluded patients with significant comorbidities and ASA more than 2 and when patients were malnourished.

ERAS protocol for gastrectomy is still subject to evolution in terms of component modification and clinical significance. Another vital aspect of success of FTS is the requirement of cooperation between the multidisciplinary team involving the surgeon, anaesthetist, nursing staff, physiotherapists and the caregivers.

METHODOLOGY

STUDY SETTING

This study was conducted in the department of Surgery, unit III, Christian Medical College Hospital, and Vellore.

STUDY DURATION

November 2013 to July 2015

STUDY DESIGN

The study was an observational cohort including patients with diagnosed adenocarcinoma stomach and were undergoing partial gastrectomy under the department of surgery 3 in Christian Medical College Hospital, Vellore.

INSTITUTIONAL REVIEW BOARD AND ETHICS COMMITTEE APPROVAL

The study design and the methodology was assessed by the institutional review board and the ethics committee and duly approved. The copy of the approval form is enclosed (Annexure - 1).

CONSENT

Patients diagnosed with carcinoma stomach and planned for subtotal gastrectomy were invited to take part in the study and the informed consent was presented in the native language. The consent forms used in the study is enclosed. (Annexure - 2)

INCLUSION CRITERIA

All adult patients with a confirmed tissue diagnosis of adenocarcinoma stomach, who underwent elective subtotal gastrectomy at the Surgery 3 unit in CMCH during the study period were included.

EXCLUSION CRITERIA

- Patients with clinical and radiological evidence of complete gastric outlet obstruction
- Patients undergoing emergency gastrectomy due to gastric perforation of an underlying malignancy.
- Patients requiring ICU admission immediate post OP due to co-morbid illnesses.

SAMPLE SIZE

Primary outcome of the study is duration of postoperative stay. On an average a patient stays in CMC following a subtotal gastrectomy for average of 7.9 days with a standard deviation of 2.5 days. Based on previous studies expected reduction in postoperative stay is 2 days with standard deviation ranging from 1.2 days.

Formula for calculation

$$N = \frac{2 \times (Z_{(1-\alpha/2)} + Z_{(1-\beta)})^2 \times \sigma^2}{D^2} \qquad \sigma^2 = \frac{S1^2 + S2^2}{2}$$

Expecting a difference of two days in the duration of hospital stay between patients following ERAS protocol when compared to the duration when ERAS is not applied, minimum sample size was calculated to be 31 for a study with power of 90% and an error of 1%.

Institution Review Board (IRB) approval was obtained prior to recruiting patients.

ERAS PROTOCOL AND METHOD OF DATA COLLECTION

All patients admitted in surgery 3 unit with a diagnosis of adenocarcinoma stomach and planned for subtotal gastrectomy were counselled regarding the study protocol and recruited. They were given handouts in their native languages which explained the protocol in detail (Annexure – 3). As there are no definite guidelines for ERAS protocol in upper gastrointestinal procedures, a protocol was developed based on the available guidelines for colonic procedures, and approved by the IRB.

The protocolentailed:

1. Preoperative interventions

Preoperative interventions consisted of counselling and information to the patients regarding ERAS protocol and the surgery. All patients were given preoperative thromboprophylaxis in the form of heparin and were provided with thromboembolic deterrent stockings. They were started on incentive spirometry and also counselled regarding cessation of smoking and consuming alcohol.

2. Intraoperative interventions

All the recruited patients underwent standard surgical procedure – subtotal gastrectomy with D1 plus or D2 lymph nodal clearance. They received prophylactic antibiotics – cephazolin, gentamicin and metronidazole during induction, as per the unit protocol. All patients received general anaesthesia with thoracic epidural analgesia with bupivacaine and fentanyl which was continued postoperatively and administered through premixed syringes. Type of resection, whether curative of palliative, intraoperative adverse events if any were monitored along with intravenous fluids administered during the procedure and blood loss were recorded.

3. Postoperative interventions

These interventions included targets regarding oral feeding and ambulation for each postoperative day. Nasogastric tube was supposed to be removed within 24 hours along with starting of sips of fluids on the same day of operation. Patients were also encouraged to sit up on the same day of surgery followed by progressive ambulation on each day. Oral sips were increased on second postoperative day and progressed to fluids as tolerated by fourth postoperative day. They were started on solid diet by fifth postoperative day. Postoperative pain relief was achieved by epidural infusion with addition of non-steroidal anti-inflammatory drugs or opioids if pain relief was inadequate as per decision of operating surgeon. Epidural infusion was continued till fourth postoperative day if it was effective and was removed along with removal of urinary catheter.

Protocol for ERAS (Table 4)

PREOPERATIVE
• **Counselling the patient and relatives regarding the disease, proposed surgery, protocol for ERAS and its advantages. (handout)**

- **Counselling patients to quit smoking and alcohol use.**
- **Training patients to do incentive spirometry.**
- **First dose of DVT prophylaxis.**

INTRAOPERATIVE

- **Anaesthesia – Endotracheal intubation and GA + Thoracic Epidural (Fentanyl + Bupivacaine). (other modes of regional analgesia if needed)**
- **Antibiotic prophylaxis at induction of anaesthesia.**
- **Avoid hypothermia during surgery**
- **Intra OP fluid restriction. (in conjunction with anaesthetist)**
- **Avoid NG tube and drains whenever possible (unless specifically deemed necessary)**

POSTOPERATIVE

- **Perioperative oxygen therapy – till 6hours post OP**
- **Incentive spirometer once the patient is awake.**
- **Analgesia – thoracic epidural analgesia ((Fentanyl + Bupivacaine)) + intravenous paracetamol (Inj Febrinil) till 48 hours. Add on non-**

opioid analgesics if pain scores more than 5 on a visual analogue score.

- **Diet – start on few sips of clear fluids on day of surgery followed by liquid diet from day 2 progressing to soft solid diet from day 4.**
- **Removal of NG tube (if present) – within 24 hours**
- **Removal of Urinary catheter – within 48 hours (along with epidural)**
- **Ambulation – mobilize to chair on day of surgery, start progressive ambulation from day 2.**
- **Continue DVT prophylaxis.**

Type of surgery and the limit of resection – standardized

Patients were considered to be fit for discharge when they satisfied the criteria for discharge (Table - 2). The day of passage of flatus and stool was also recorded for each patient.

Table 5 - Criteria for discharge

- **Normal body temperature,**
- **Pain controlled with oral analgesics,**
- **Mobilizing comfortably**
- **Adequate oral diet , without parenteral fluids**

Patients included in the study group were followed up postoperatively and adherence to the ERAS protocol was observed. Any deviation from the protocol was noted along with the reason for the same. Postoperatively these patients were followed up till discharge for any immediate complications and later on as outpatient for any delayed complications. Complication was classified according to the Clavien Dindo classification system(103).

ANALYSIS

Data was collected by interview technique using questionnaire for the demographic details and adherence to protocol was recorded. (Annexure - 3) Patients were followed up till their immediate postoperative outpatient visit. Data regarding adherence to ERAS protocol was collected by daily

postoperative follow up and entered on investigation form (Annexure -) Data was entered using epidata software and analysed using STATA software.

RESULTS

Forty four patients diagnosed with adenocarcinoma of distal stomach were recruited prospectively for the study. They were counselled regarding the study protocol. According to the protocol they were given preoperative incentive spirometry and thromboprophylaxis, intraoperative events were recorded and postoperative targets as per the protocol were monitored. Their adherence to the protocol was recorded and were followed up till discharge and first outpatient follow up. Any deviation from the protocol was recorded along with the reason for the same. This was compared to historical controls from the previous year for whom data was collected from the inpatient charts. The results were analysed as

1. Demographic parameters in both groups

2. Effectiveness of ERAS protocol

3. Adherence to ERAS protocol

DEMOGRAPHIC PARAMETERS

- AGE

Mean age among the ERAS group was 54.09 as compared to 50.50 in the control group (Table 1).

Table 1 – Age distribution

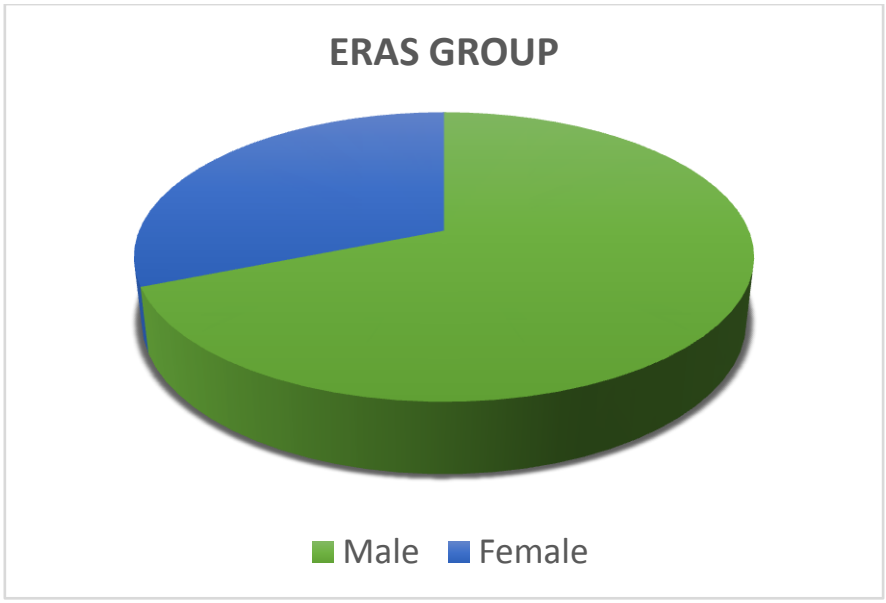
Group	Mean Age	Standard deviation
ERAS Group	54.09	12.16
Control Group	50.5	13.47

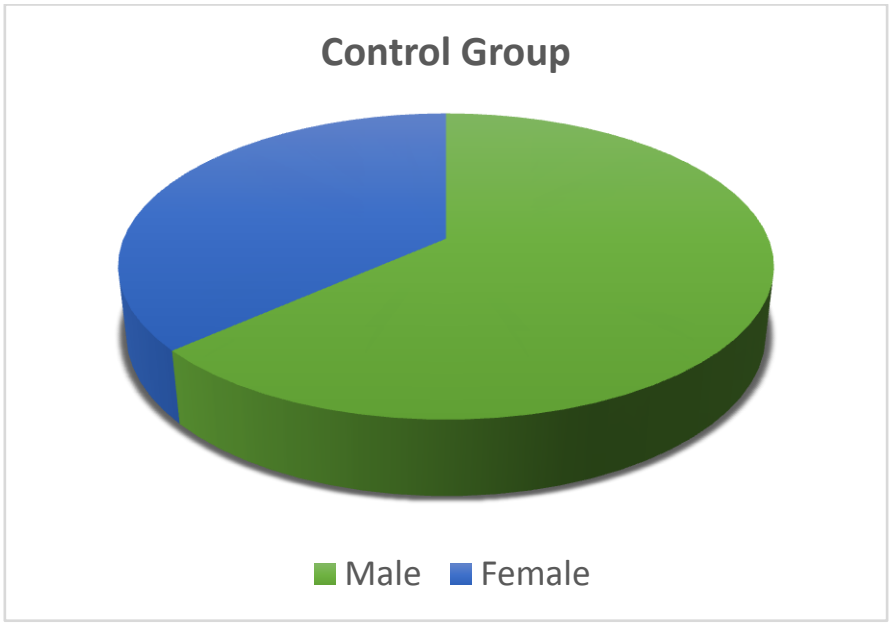
- GENDER

Both ERAS group and the control group consisted of more males as compared to females. (Table -2, Fig – 1)

Table 2 – Gender distribution

Gender	Male	Female
ERAS Group	30	14
Control Group	26	15



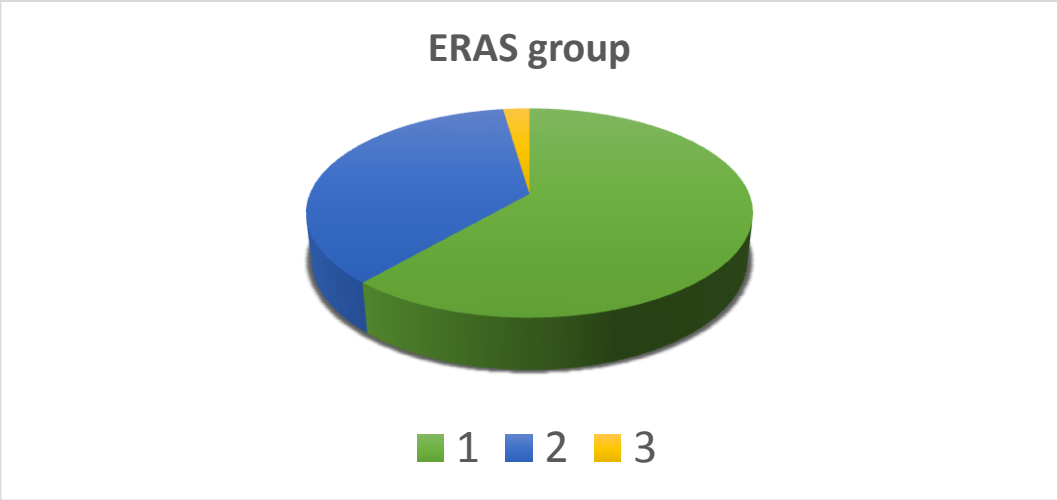


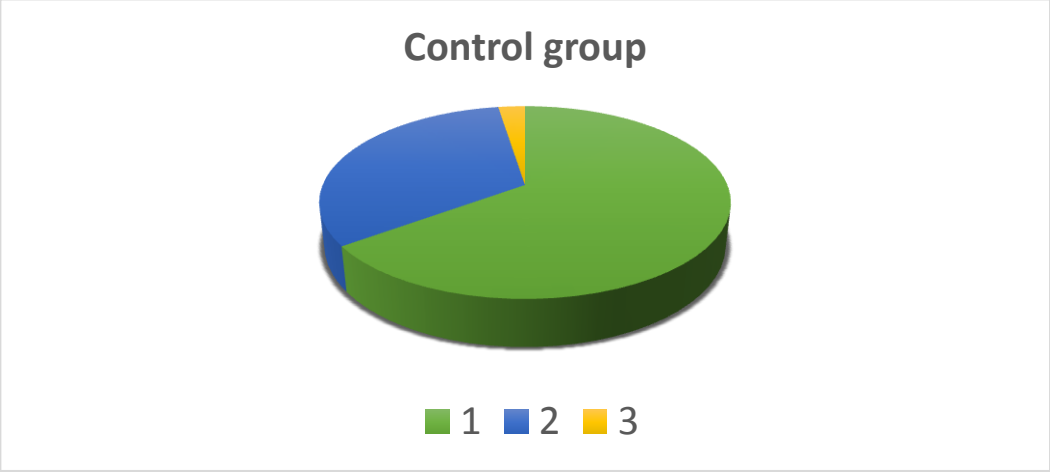
- FITNESS STATUS OF PATIENTS

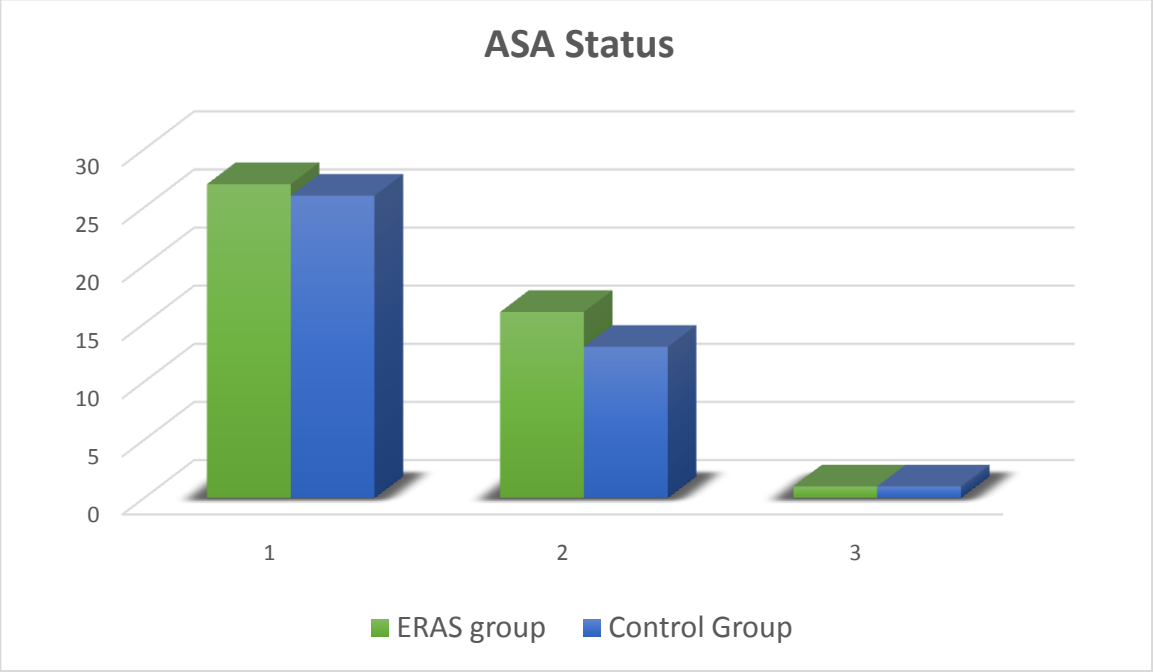
Among the patients studied in the ERAS group and the control group, general fitness was assessed with the American Society of Anaesthesiologists (ASA) status score for physical fitness.

Table 3 – ASA status of patients in study

ASA Status	ERAS group	Control Group
1	27	26
2	16	13
3	1	1

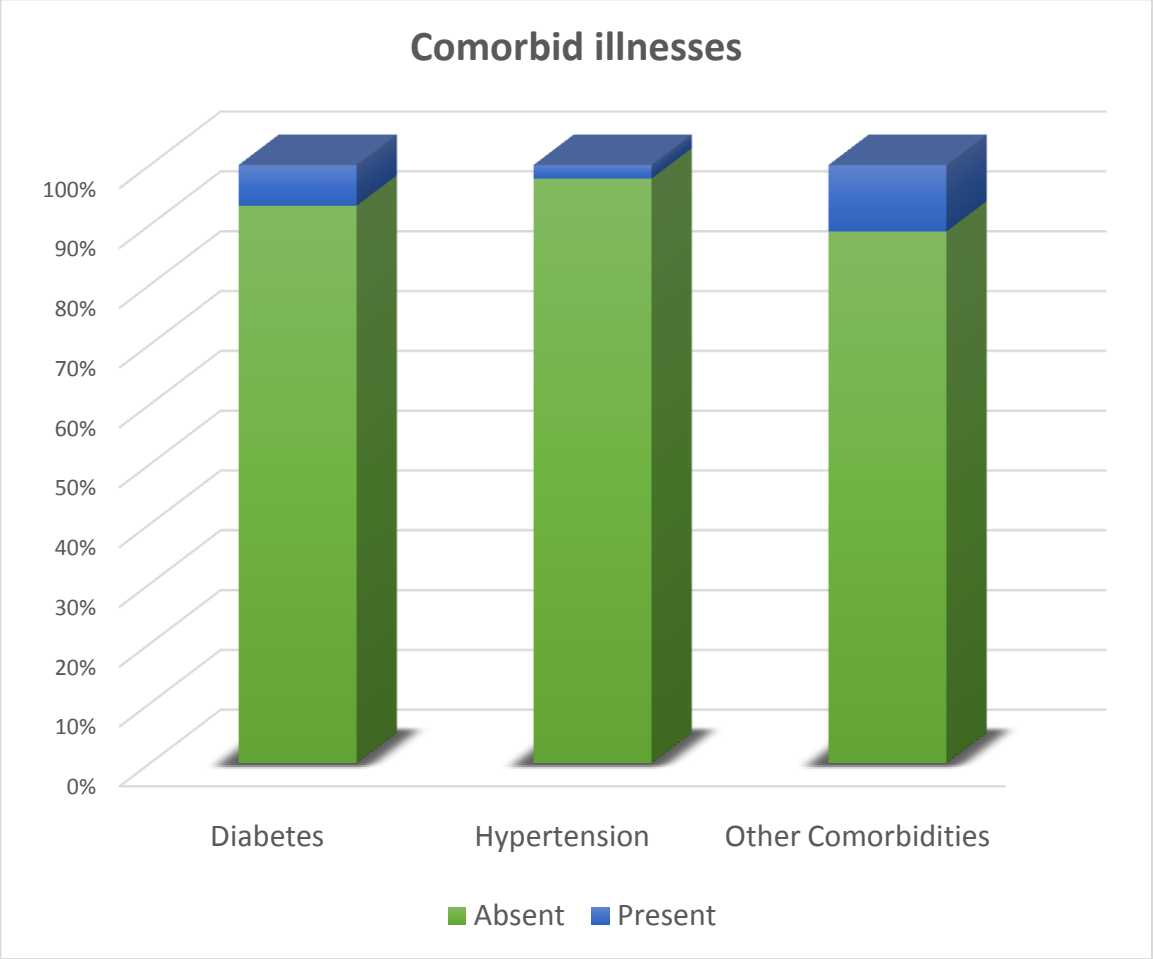






- COMORBID ILLNESSES

Among the ERAS group, three out of the forty four patients had diabetes. One among the group had hypertension. Five patients had other comorbidities which included hypothyroidism and bronchial asthma.



DISEASE CHARECTERISTICS

All patients in the ERAS and control group were diagnosed to have adenocarcinoma of the distal stomach.

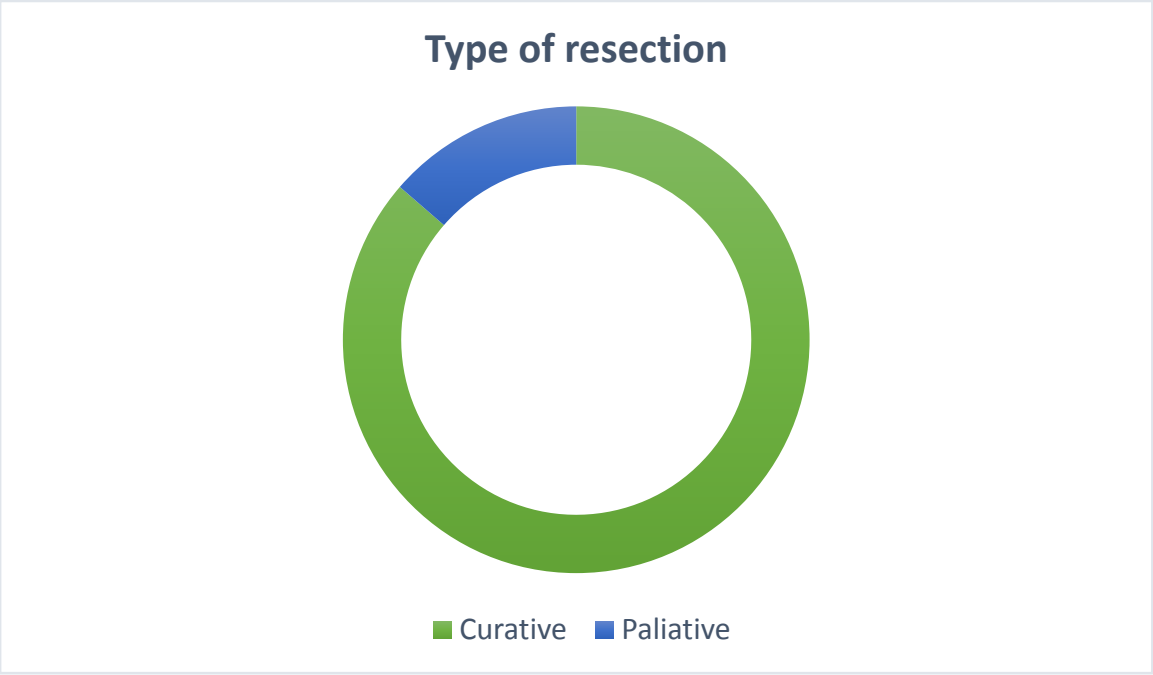
- DURATION OF SYMPTOMS

Among the patients in ERAS group, average duration of symptoms prior to the operation was 9.55 months.

Duration of Symptoms	Mean	Standard Deviation
Months	9.55	12.37

- Type of resection

Thirty eight of the forty four patients underwent curative resection, however six patient had palliative resection.



EFFECTIVENESS OF ERAS

Duration of postoperative hospital stay was calculated from the day surgery to the day when they were fit for discharge. Median duration of stay in the ERAS group was found to be 6 days and in the control group was 7 days. On analysis with Mann-Whitney test the difference in hospital stay was found to be not significant (P value – 0.055).

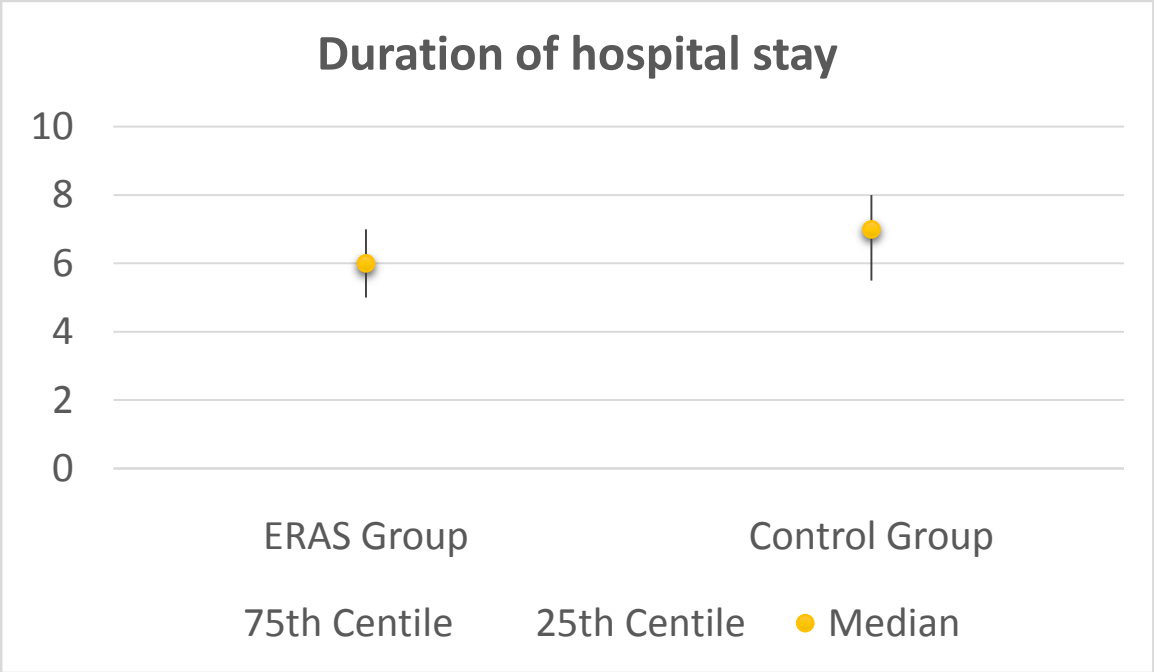
Table 5 – duration of postoperative hospital stay

	25th centile	**Median stay**	**75th centile**
ERAS group	5 days	6 days	7 days
Control group	5.5 days	7 days	8 days

On analysis of duration of total hospital stay from the date of admission to the date of discharge, median stay in the ERAS group and control group was 8 days and 9 days respectively but the difference was not statistically significant (P value – 0.056).

Table 6 – Total duration of hospital stay

Total duration of hospital stay	25th centile	Median stay	75th centile
ERAS group	7 days	8 days	10 days
Control group	8 days	9 days	12 days



ADHERENCE TO ERAS PROTOCOL

- PREOPERATIVE STRATEGIES

Adherence to preoperative protocol was 100 percentage. All patients were counselled about the procedure and about postoperative targets. They

were also started on incentive spirometry, and received prophylactic dose of heparin as thromboprophylaxis. Patients with smoking and alcohol consumption were advised cessation of the same.

Protocol	Adherence
1. **Preoperative counselling and information**	100%
2. **Advice regarding cessation of stoppage of smoking and alcohol**	100%
3. **Incentive spirometry**	100%
4. **Preoperative heparin prophylaxis**	100%

- INTRAOPERATIVE STRATEGIES

All patients received general anaesthesia plus thoracic epidural analgesia with bupivacaine and fentanyl. They also received one dose of prophylactic antibiotic (cephazolin + gentamicin + metronidazole) at the time of induction.

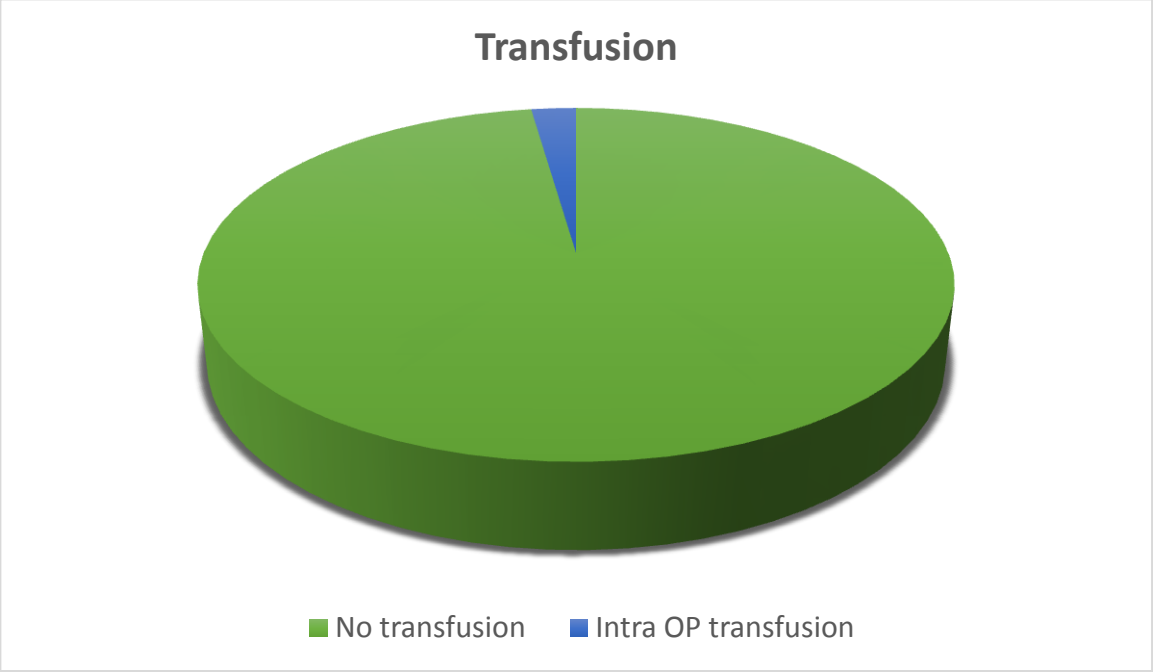
They were monitored throughout the procedure with temperature probe and none of the patients had any evidence of hypothermia.

Intraoperative strategy	Adherence in patients
1. **Anaesthesia – GA + epidural**	100%
2. **Prophylactic antibiotics**	100%
3. **Hypothermia**	Nil

None among the forty four patients had any intraoperative complications. The average blood loss during the procedure in these procedures was 127.9ml and they received an average of 1614ml fluids intraoperatively. One patient required blood transfusion intraoperatively as the preoperative haemoglobin was less.

Table 7 – blood loss and intravenous fluids

Parameter	Mean	Standard deviation
Blood loss	127.93	109.01
Intra OP fluids	1614.25	653.17

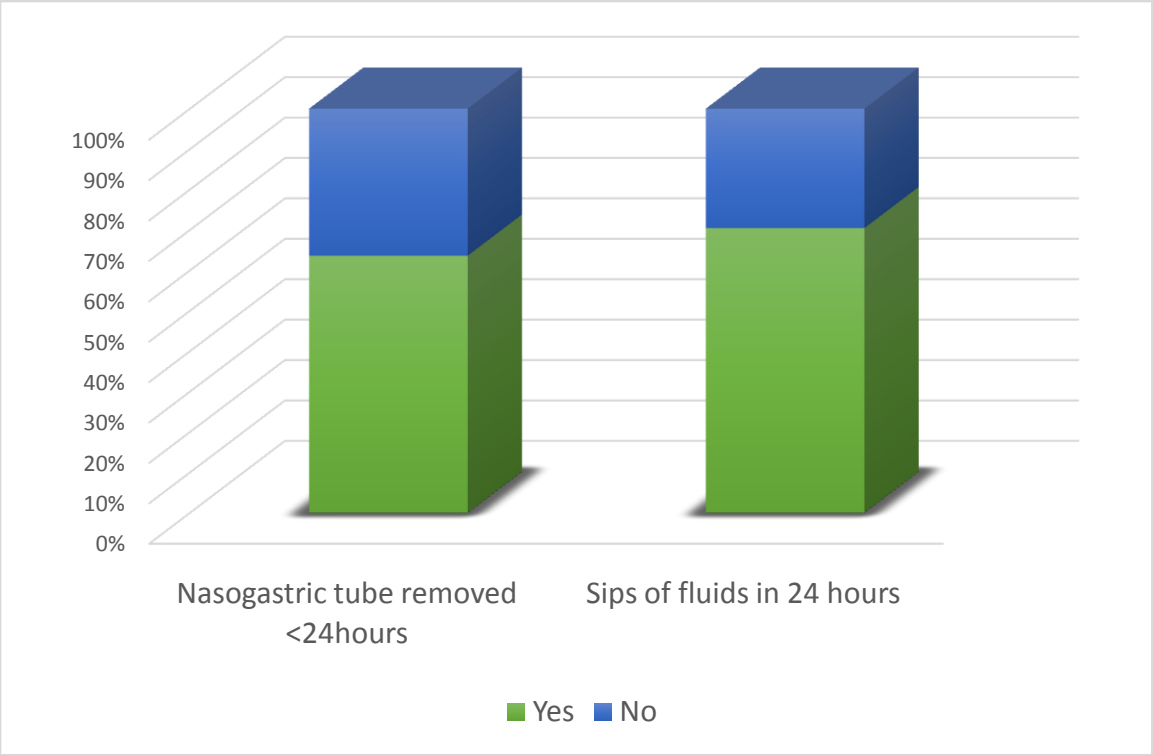


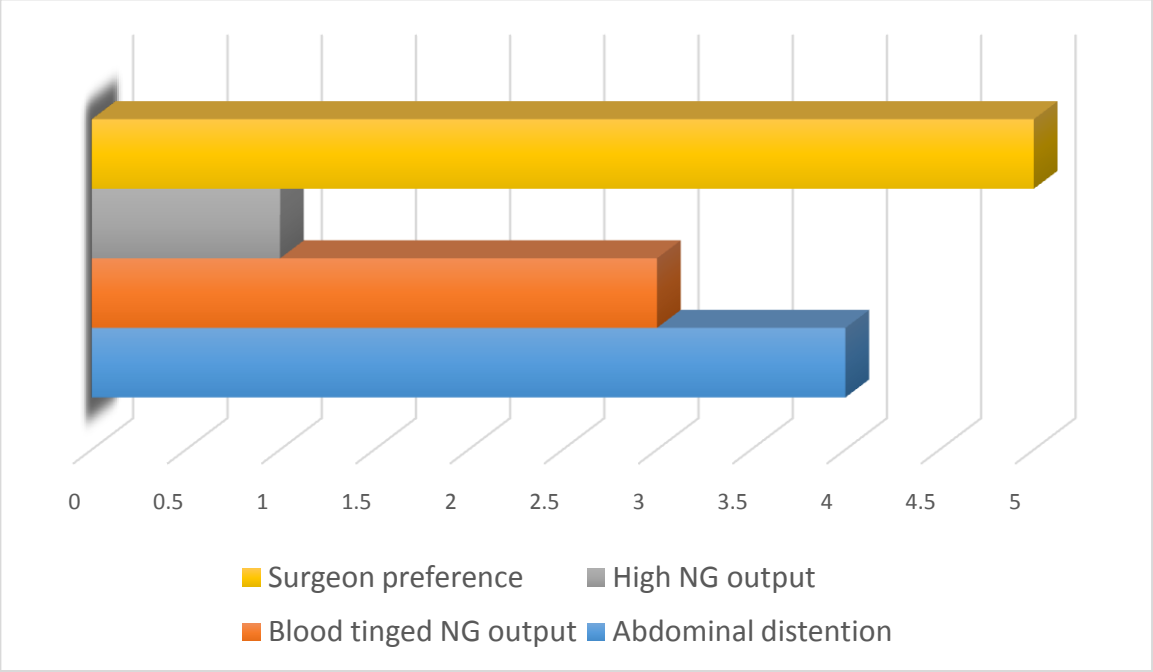
POSTOPERATIVE PARAMETERS AND ADHERENCE TO PROTOCOL

- Nasogastric tube and Initiation of diet within 24 hours

One patient had the nasogastric tube removed immediately after surgery and the remaining forty three patients had nasogastric tube retained after surgery. 63.6% of patients had the nasogastric tube removed within 24 hours of surgery. 70.45% patients were started on sips of fluids within 24 hours. Among the patients for whom nasogastric tube was not removed and oral fluids were not started, three patients had blood stained nasogastric

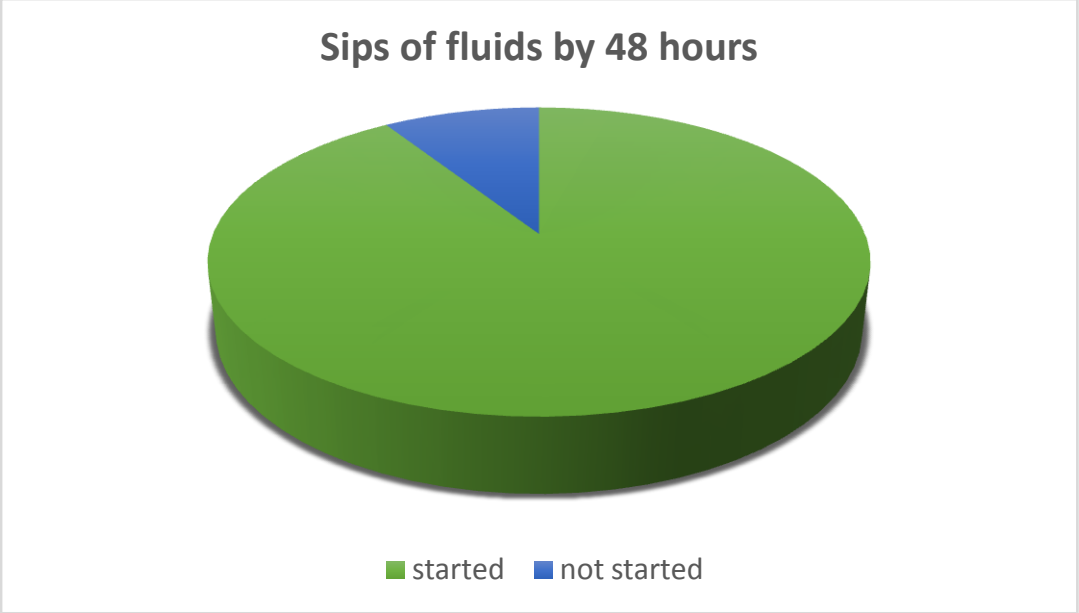
output, one patient had high output. For 5 patients nasogastric tube was retained due to surgeon preference and the remaining had abdominal distention and hence not started on fluids.





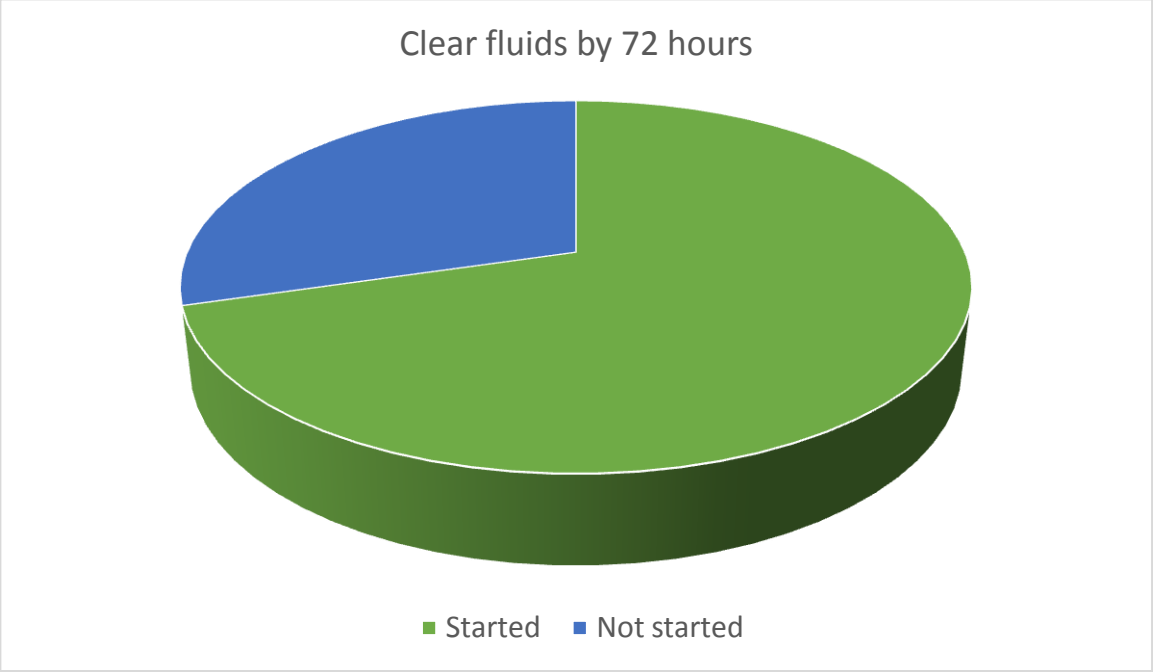
- Oral fluids by 48 hours

By 48 hours, 72.7 percentage of patients were started on sips of fluids. Most common reason for not starting fluids orally remained to be persistent abdominal distention and reluctance of operating surgeon to start oral fluids.



- Increase in oral fluid intake by 72 hours

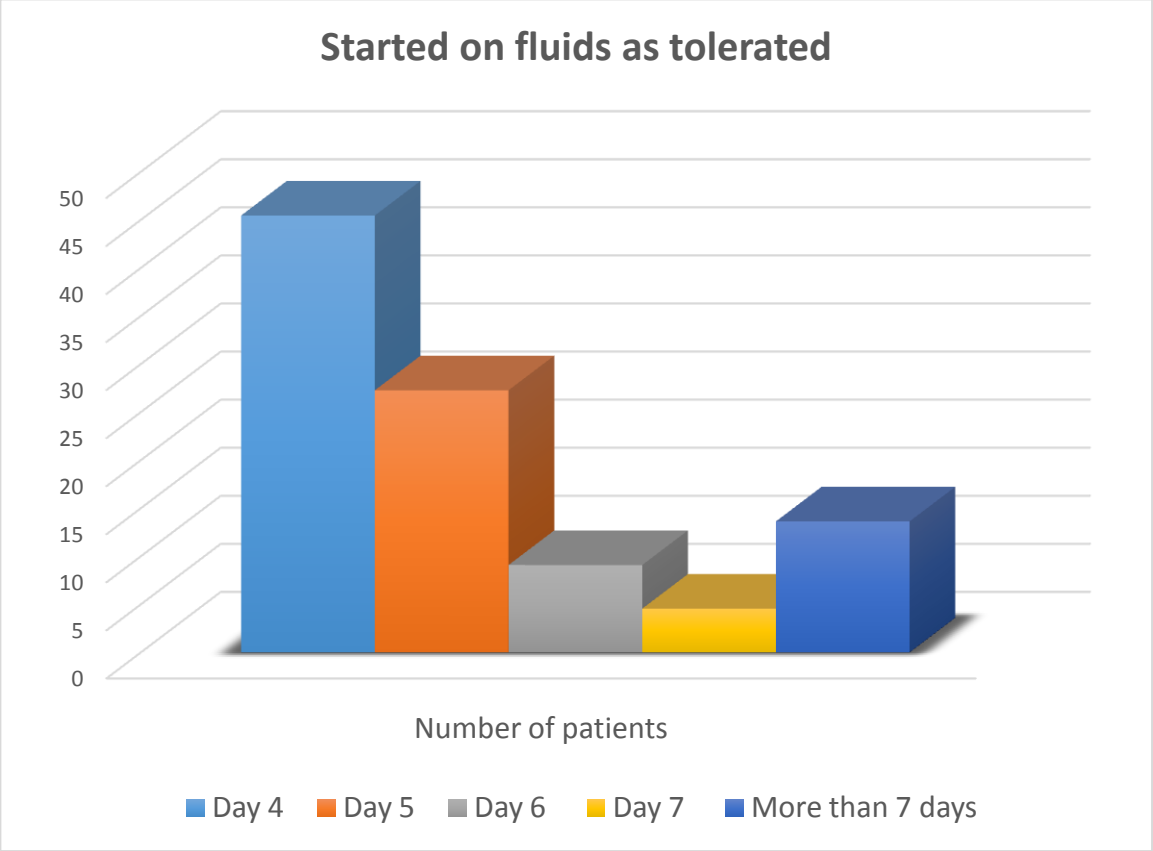
70.45% of patients tolerated clear liquids 30-60 ml per hour by 72 hours. One patient who was started on sips of fluidswas not progressed to clear fluids and had to be continued on sips of fluids as he had abdominal distention.



- Day of starting fluids as tolerated

45.45% of the patients were tolerating liquids adequately by 4th postoperative day. By 5th day, 72.73% patients were tolerating fluids.

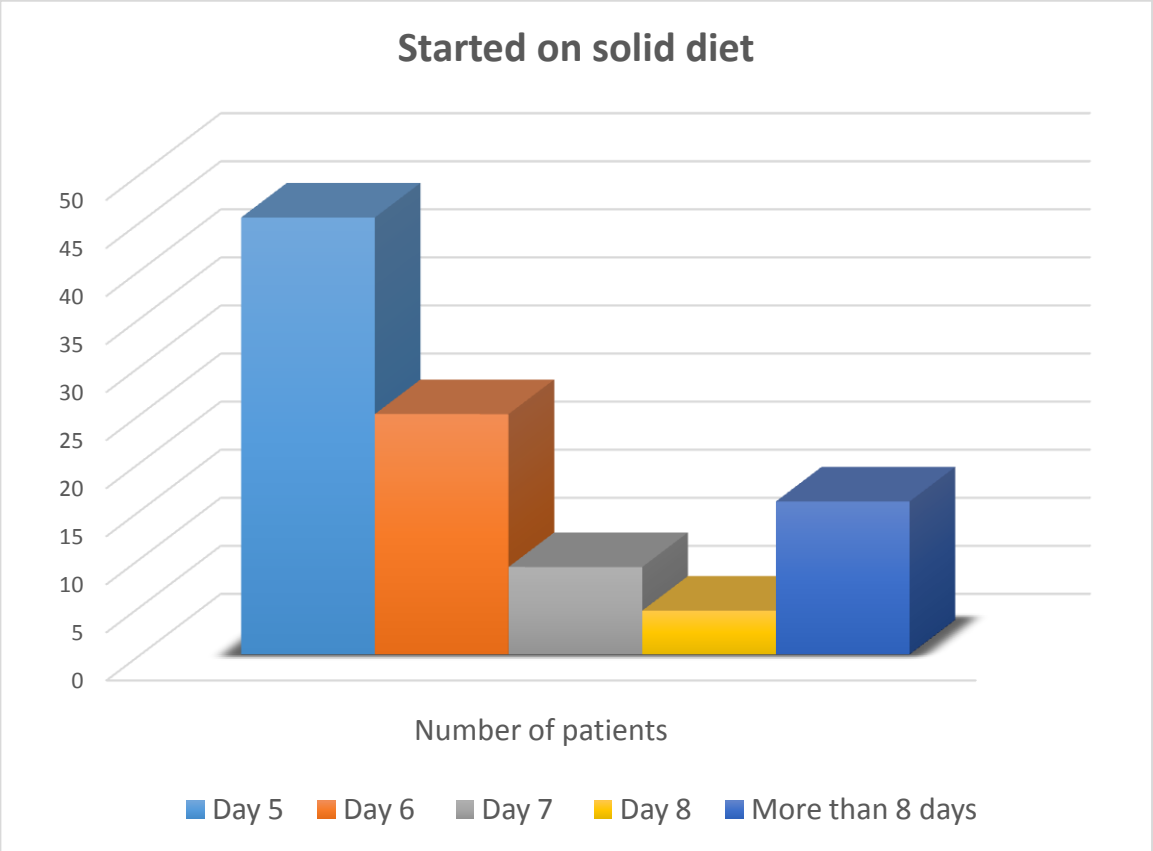
Fluids as tolerated	Number of patients	Percentage
Day 4	20	45.45
Day 5	12	27.27
Day 6	4	9.09
Day 7	2	4.55
> 7 Days	6	13.63



- Initiation of solid diet

45.45 percentage of patients were started on solid diet by fifth postoperative day. 70.45 percentage of patients tolerated normal diet by sixth postoperative day. 15.9 percentage of patients were not started on solid diet by 8 days. This group included the patients who developed complications in the postoperative period. One patient tolerated liquids but developed intolerance to solid diet and had a nasojejunal tube inserted for feeding.

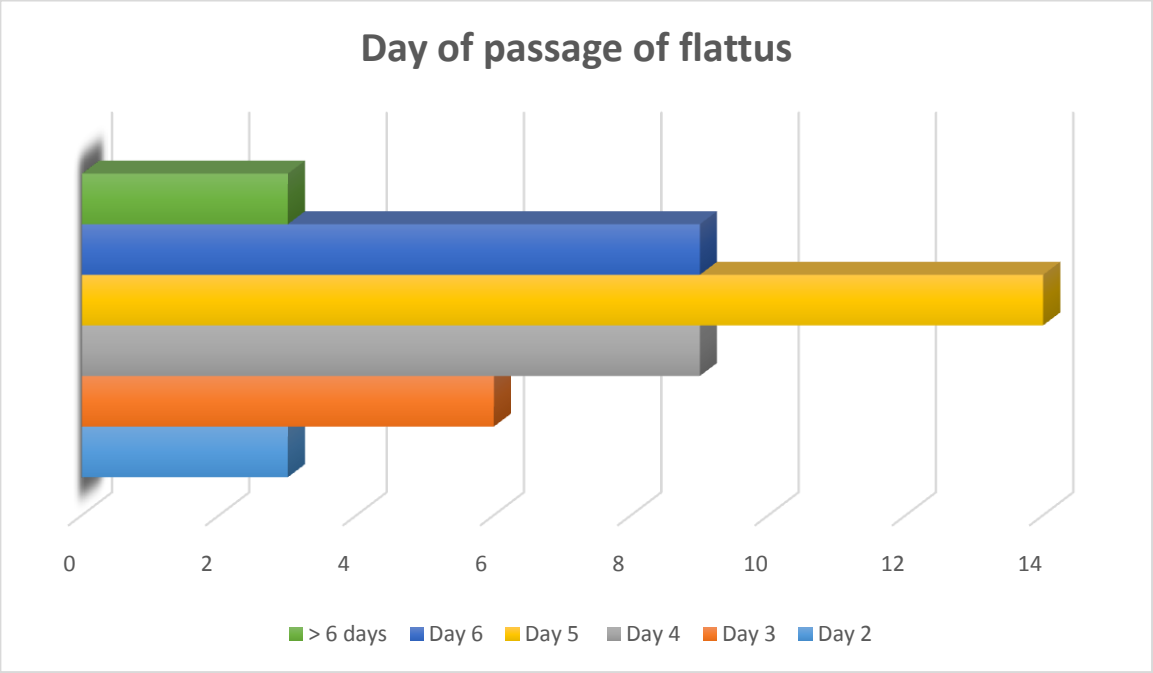
Solid	Number of patients	Percentage
Day 5	20	45.45
Day 6	11	25.00
Day 7	4	9.09
Day 8	2	4.55
> 8 Days	7	15.91



- Passage of flatus and stools

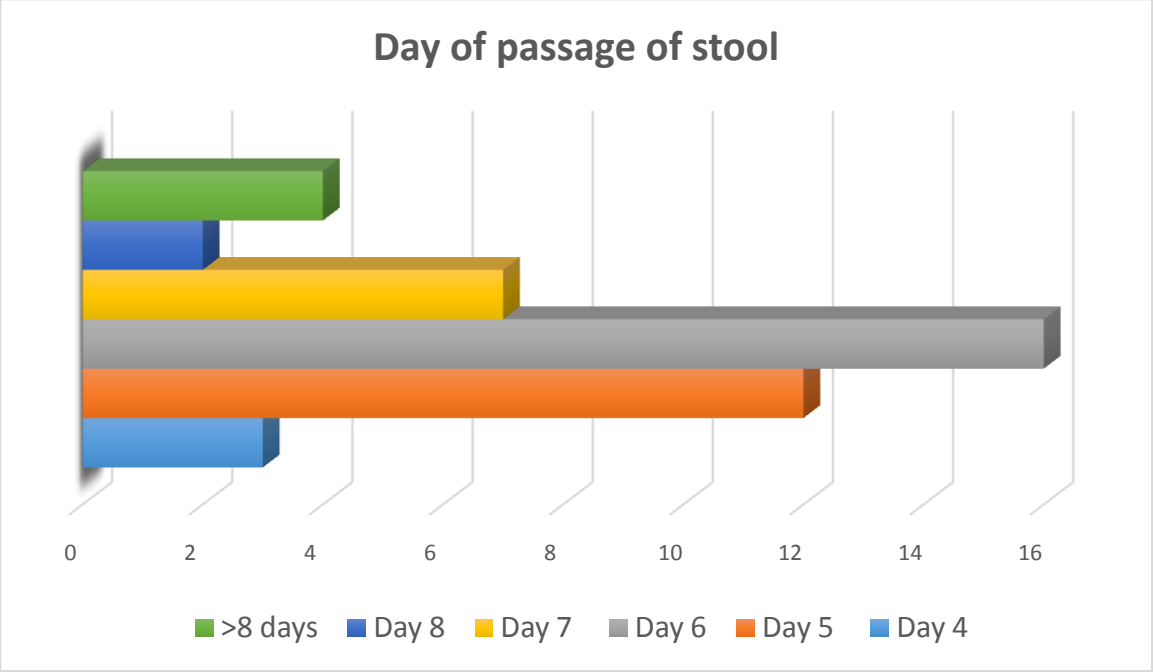
72.73 percentage of patients had passed flatus by fifth postoperative day and all patients other than three who required re-exploration in the postoperative period had passed flatus by sixth postoperative day.

Day of passage of flatus	Number of patients	Percentage	Cumulative percentage
Day 2	3	6.82	6.82
Day 3	6	13.64	20.45
Day 4	9	20.45	40.91
Day 5	14	31.82	72.73
Day 6	9	20.45	93.18
➢ **6 days**	3	6.82	100



70.45 percentage of patients passed stools by 6 days and 86 percentage of patients had passed stools by 7th postoperative day.

Day of passage of stools	Number of patients	Percentage	Cumulative percentage
Day 4	3	6.82	6.82
Day 5	12	27.27	34.09
Day 6	16	36.36	70.45
Day 7	7	15.91	86.36
Day 8	2	4.55	90.91
>8 days	4	9.09	100



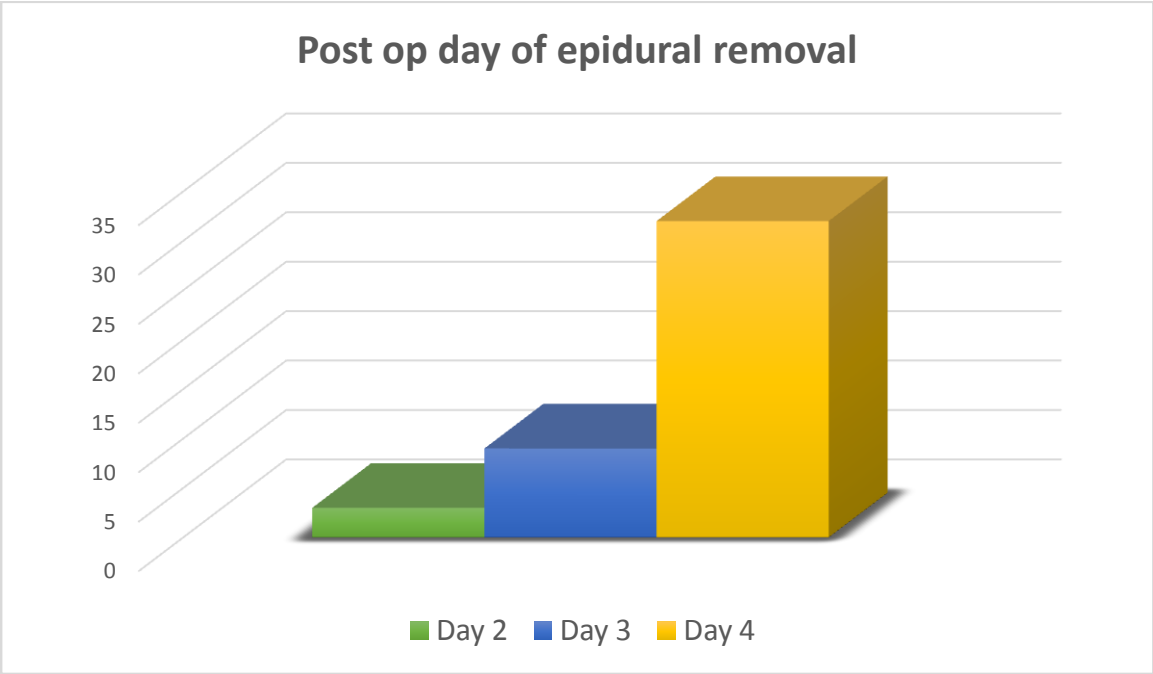
- Ambulation and postoperative pain relief

All patients in the group followed the protocol for ambulation. All patients were made to sit up for at least half an hour in the initial 24 hours and were encouraged to ambulate from the day of surgery. Ambulation was progressively increased over the postoperative period.

All patients received epidural analgesia for post op pain relief. None of the patients required any additional opioid for pain relief however few patients were given additional non-steroidal anti inflammatory drugs after assessment by the operating surgeon to top up analgesia. 72.73 percentage of patients had epidural analgesia retained till 4^{th} post-operative day. Three patients had to be given morphine

subcutaneous doses for pain relief as the epidural had to be removed before 48 hours due to hypotension.

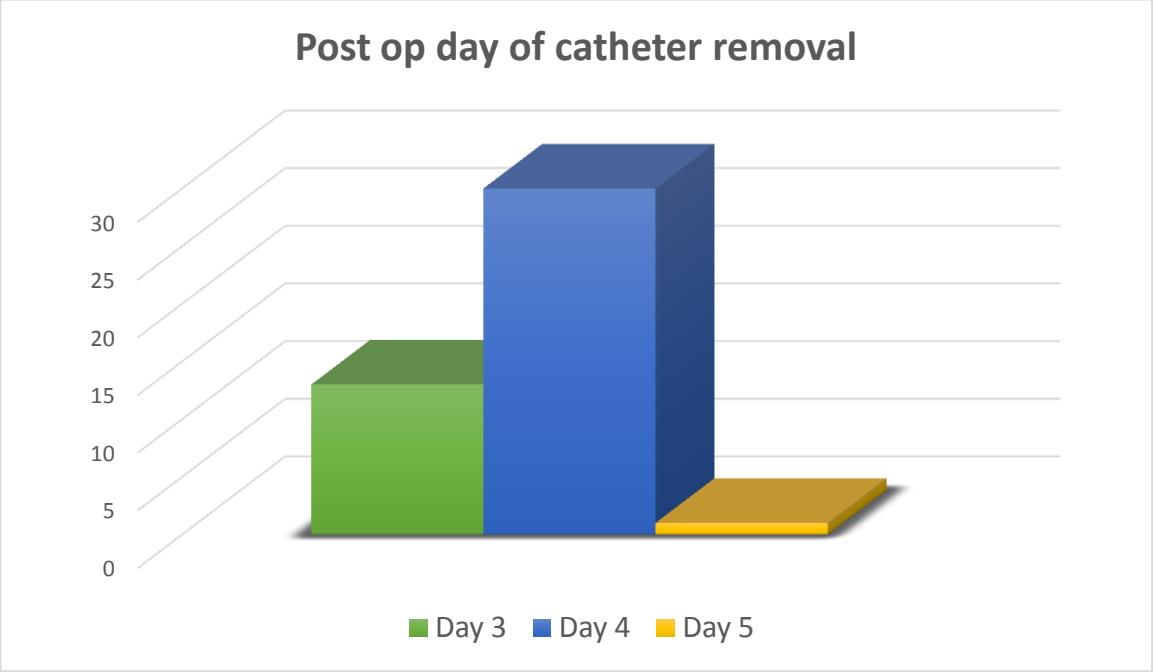
Day of epidural removal	Number of patients	Percentage
2	3	6.82
3	9	20.45
4	32	72.73



- Urinary catheter

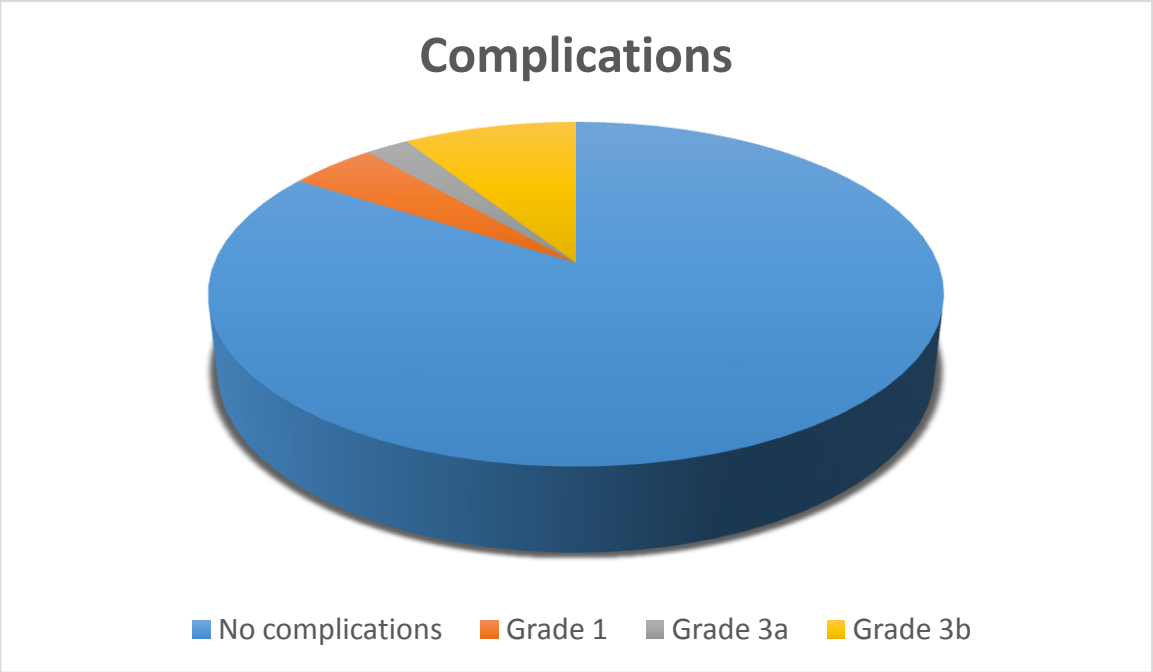
97 percent of patients had their urinary catheter removed by 4th postoperative day.

Day of catheter removal	Number of patients	Percentage
3	13	29.55
4	30	68.18
5	1	2.27



COMPLICATIONS

Immediate post-operative complications among the patients in ERAS group were studied and classified according to Clavien Dindo grading for postoperative complications into mild (grade 1 and 2) and severe (3 and 4).Four patients required re-laparotomy (Grade 3b) and one patient re admission due to sub diaphragmatic collection requiring radiology guided drain placement (Grade 3a). Two patients developed wound infection which was managed with dressings (Grade 1) but prolonged their hospital stay. According to other studies, morbidity following subtotal gastrectomy ranges from 9 to 16 percentage(104,105). In our study percentage of patients requiring repeat laparotomy was 9.09%. There was no mortality among the group.



DISCUSSION

Demographic details of the ERAS group and control group were comparable. The mean age group among the groups were comparable to other international studies which showed predominance in the later age group with incidence increasing after 50 years of age.Multiple studies had also shown male preponderance for intestinal type of gastric cancer up to 2:1(106). The results of this study also showed similar distribution. Majority of patients who were operated belonged to ASA 1 status with the percentage of patients with comorbid illnesses being very less. Due to the number of patients with comorbidities being very less any form of multivariate analysis to study the effect of comorbid illnesses on the outcome and relation to ERAS protocol could not be assessed.

This study proved that although there was a difference in postoperative hospital stay among patients following ERAS protocol for gastrectomy as compared to the conventional group, the difference was not statistically significant. This result was contradictory to similar international studies including a recent meta-analysis which showed significant reduction in postoperative hospital stay. This could be attributed to various possible reasons

1. There has not been any study reported from the Indian population. The difference in response to the ERAS protocol may be explained by the difference in the disease and patient characteristics and the reluctance to change from the conventional postop care resulting in reduced adherence to protocol.
2. Sample size being small could be one reason for the difference in hospital stay not being statistically significant.
3. Although ERAS was not being followed as a protocol, conventional care had incorporated various components of ERAS like nasogastric tube removal and early ambulation. Hence although not as a protocol, ERAS was partially being implemented in the conventional group, making the difference less significant.
4. Another possible explanation is that patients were retained longer than the ideal required time due to error in recording the time when the patient was 'fit for discharge' as per the agreed protocol due to surgeon preference/patient reluctance to leave.

Adherence to the ERAS protocol was 100 percent for the preoperative interventions. There were no intraoperative adverse events. Patients received an average of 1614ml fluids intraoperatively

which is comparable to other similar studies. During postoperative period, 63.6% of patients had nasogastric tube removed in 24 hours and 70.45% patients were started on sips of fluids from the day of surgery. Reduced adherence to the removal of nasogastric tube was partly due to reluctance of the operating surgeon to start enteral feeds early and due to intolerance to enteral feeding detected as persistence of abdominal distention.72.7 percentage of patients were on sips of fluids by forty eight hours. Except for one patient among the group which was started on fluids all others had progressed to increased fluids orally. 72.73% patients were tolerating liquids as tolerated by fifth postoperative day. Six patients were requiring supplementary intravenous therapy even after 7 days postoperatively.These were the patients who required re-exploration and one patient who had abdominal distention after starting fluids and had to have reinsertion of nasogastric tube. More than 70% of the patients were tolerating solid diet by sixth postoperative day.

More than 70% patients had passed flatus by fifth postoperative day and more than 90% by sixth postoperative day.70% patients had passed stools by day 6 postoperatively and more than 90% had passed stools by day 8.

All patients were ambulated according to the protocol. All patients tolerated early ambulation. Pain relief was adequate with epidural analgesia with topped up with non-steroidal anti-inflammatory agents whenever required. For majority of patients (7.73%) the epidural analgesia was retained till fourth postoperative day. Urinary catheter was also retained till epidural was continued for majority of patients.

Among the 44 patients, four patients required re-laparotomy of which three patients had duodenal stump leak and one patient had leak from the gastro jejunostomy site. One patient required readmission for sub-diaphragmatic collection. There was no mortality among the group and significant morbidity (Grade 3 and 4) was 9.09 percentage which was comparable to international literature.

LIMITATIONS

1. As the sample size was small, statistical significance could not be demonstrated for the durationof hospital stay even though there was a observed difference.

2. The study being an observational cohort and controls being historical cohort from preceding year, complete details could not be compared with the control group due to missing data.

3. There is no definite consensus on ERAS protocol for upper gastrointestinal procedures. Different studies till now have used modified protocols from colorectal surgeries.

4. As the sample size was less, multivariate analysis did not yield any significant results.

5. The study was an observational study hence the protocol was not strictly implemented and had variations based on surgeon preference.

CONCLUSIONS

1. The duration of hospital stay following subtotal gastrectomy is reduced when ERAS protocol has been followed however the difference was not statistically significant.

2. Following an enhanced recovery protocol did not have any adverse effect on immediate postoperative morbidity or mortality.

3. Overall compliance to the ERAS protocol was good however more studies and randomised control trials among Indian population will be required to formulate a proper guideline for ERAS in gastrectomy.

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Annexure

1. IRB Approval Letters
2. Informed Consent Forms
3. Patient Handout
4. Investigation Proforma
5. Data Recording Form
6. Data Sheets

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Glas) (EDIN)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

January 17, 2014

Dr. Nandu Nair
PG Registrar
Department of General Surgery
Christian Medical College, Vellore 632 002

Sub: **Fluid Research grant project:**
Enhanced Recovery Protocol for Subtotal Gastrectomy: A prospective cohort to assess whether post-operative recovery following subtotal gastrectomy can be enhanced by following a structured protocol.
Dr. Nandu Nair, General Surgery, Dr. Vijay Abraham, General Surgery, Dr. Sudhakar Chandran, General Surgery, Dr. Inian Samarasam, General Surgery, Dr. Myla Yacob, General Surgery.

Ref: IRB Min. No. 8560 [OBSERVE] dated 12.11.2013

Dear Dr. Nandu Nair,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
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Cc: Dr. Vijay Abraham, General Surgery, CMC

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January 17, 2014

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Department of General Surgery
Christian Medical College,
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Ref: IRB Min. No. 8560 [OBSERVE] dated 12.11.2013

CHRISTIAN MEDICAL COLLEGE
VELLORE
INDIA

Dear Dr. Nandu Nair,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Enhanced Recovery Protocol for Subtotal Gastrectomy: A prospective cohort to assess whether post-operative recovery following subtotal gastrectomy can be enhanced by following a structured protocol." on November 12th 2013.

The Committees reviewed the following documents:

1. IRB application format
2. Curriculum Vitae' of Dr. Nandu Nair, Dr. Vijay Abraham, Dr. Sudhakar Chandran, Dr. Inian Samarasam, Dr. Myla Yacob
3. Informed Consent form (English, Hindi, Tamil & Bengali)
4. Information sheet (English, Hindi, Tamil & Bengali)
5. No of documents 1-4

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Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on November 12th 2013 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Name	Qualification	Designation	Other Affiliations
Dr. Simon Rajaratnam	MBBS, MD, DNB (Endo), MNAMS (Endo), PhD (Endo), FRACP	Professor, Endocrinology, CMCH.	Internal, Clinician
Dr. T. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMCH.	Internal, Clinician
Dr. Chandra Singh	MS, MCH, DMB	Professor, Urology, CMCH.	Internal, Clinician
Dr. Visalakshi	MPH, PhD	Lecturer, Dept. of Biostatistics, CMC.	Internal, Statistician
Dr. Benjamin Perakath	MBBS, MS, FRCS	Professor, Colorectal Surgery, CMCH.	Internal, Clinician
Dr. Anup Ramachandran	Ph. D	The Wellcome Trust Research Laboratory Gastrointestinal Sciences, CMCH.	Internal, Basic Medical Scientist
Dr. Mathew Joseph	MBBS, MCH	Professor, Neurosurgery, CMCH.	Internal, Clinician
Dr. Rajesh Kannangai	MD, Ph D.	Professor & In-charge Retrovirus Laboratory (NRL under NACO), Department of Clinical Virology, CMCH.	Internal, Clinician

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Glas) (EDIN)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

Mrs. Pattabiraman	B. Sc, DSSA	Social Worker, Vellore	External, Lay person
Mr. C. Sampath	B. Sc, BL	Legal Expert, Vellore	External, Legal Expert
Rev. Joseph Devaraj	B. Sc, BD	Chaplaincy Department, CMCH.	Internal, Social Scientist
Dr. Vathsala Sadan	M.Sc, PhD	Professor, Community Health Nursing, CMCH.	Internal, Nurse
Dr. Ebenezer Ellen Benjamin	M.Sc, PhD	Professor, Maternity Nursing, CMCH.	Internal, Nurse
Dr. B. J. Prashantham	MA(Counseling Psychology), MA(Theology), Dr. Min (Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
Dr. Anuradha Rose	MBBS, MD	Assistant Professor, Community Health, CMCH.	Internal, Clinician
Dr. Jayaprakash Muliyil	B. Sc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, Vellore	External, Scientist & Epidemiologist
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL	Sr. Legal Officer, CMCH.	Internal, Legal Expert
Dr. Nihal Thomas,	MD, MNAMS, DNB(Endo), FRACP(Endo) FRCP(Edin) FRCP (Glasg)	Professor & Head, Endocrinology. Additional Vice Principal (Research), CMCH. Deputy Chairperson, IRB, Member Secretary (Ethics Committee), IRB	Internal, Clinician

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OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

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MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Glas) (EDIN)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

Fluid Grant Allocation:

A sum of 5,000 INR (Rupees Five Thousand only) will be granted for 21 months.

Yours sincerely

NOT TO BE MINISTERED UNTO BUT TO MINISTER
CHRISTIAN MEDICAL COLLEGE
VELLORE
INDIA

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Vijay Abraham, General Surgery, CMC

IRB Min. No. 8560 [OBSERVE] dated 12.11.2013

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
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ENHANCED RECOVERY AFTER SURGERY (ERAS)

A STUDY IN SUBTOTAL GASTRECTOMY PATIENTS

CHRISTIAN MEDICAL COLLEGE, VELLORE

INFORMATION SHEET

1. This study, in which you are being asked to participate, is being conducted to assess the effectiveness of enhanced recovery protocol after subtotal gastrectomy.

2. As part of the study, data regarding your disease will be collected using interview method and from medical records.

3. You will not have to undergo any special investigations in this study.

4. You have to strictly follow the protocol already explained to you (also provided as a hand-out).

5. Although we do not anticipate any adverse effects as a result of following this protocol, you will be constantly monitored for the development of any postoperative complications.

6. I understand that I will not be offered any financial benefits because of participation in this study.

7. The study details will be kept confidential in terms of personal information received from patients. Only the end results of the study will be published. The primary data collected will be kept in a database within General Surgery Unit 3, Christian Medical College, Vellore and will be accessible only to the doctors conducting the study.

8. Consenting to be part of the study is purely voluntary. You can withdraw from the study at any given point of time and no explanation needs to be offered regarding the same. The further course of treatment will follow the standard protocol and in no way you will be penalised for it.

9. You are eligible for the standard care offered to all patients in CMC, Vellore. None of the study patients will be deprived of the available therapies.

10. Any new information regarding the findings, if significant, will be notified to you.

In the event of any further queries about the study, risks and benefits at any point of the study, you can contact Dr. Nandu Nair at 0416 – 2282079 / 9843666901.

Informed consent form

Study Title: ERAS Protocol for Subtotal Gastrectomy.

Subject's Initials: _____ Subject's Name: _____

Date of Birth / Age: _____

Please mark √ in the boxes after reading,

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the cost of treatment and surgery I am being charged is identical to other patients not participating in this study. I am aware that I will not be offered any monetary / other benefits.

(iv) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. [ ]

(v) I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(vi) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(vii) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative
Date: _____/_____/_____
Signatory's Name: _____

Signature of the Investigator: _____
Date: _____/_____/_____
Study Investigator's Name: _____

Signature of the Witness: _____
Date:_____/_____/_____
Name of the Witness: _____

ENHANCED RECOVERY AFTER SURGERY (ERAS)

SUBTOTAL GASTRECTOMY HAND-OUT FOR PATIENTS

Aim of the leaflet

The aim of this booklet is to help you understand what enhanced recovery is and how you can and will play an active part in your recovery. It outlines what you can expect to happen on a daily basis after your operation.

What is Enhanced Recovery After Surgery?

The aim of enhanced recovery is to improve your recovery from surgery and enable you to return to normal activities as early as you are able to. The programme focusses on making sure that patients are actively involved in their recovery.

The key principles of enhanced recovery are:

- Planning and preparation for surgery.
- Reducing the stress of operation.
- Structured perioperative and postoperative care (including pain relief).
- Early mobilization and early feeding.

Before your operation

There are several things that you can do before your operation to help speed up your recovery afterwards.

Stop smoking

If you are a smoker, you should stop as soon as possible. The longer you are smoke-free before your operation, the smaller your risk of developing a chest problem after your operation. Stopping smoking will also improve your blood circulation and your body's ability to heal.

Healthy lungs - breathing exercises before your operation

Having an anaesthetic can make you produce phlegm which you need to clear once you are awake after your operation. The breathing exercises will help you open up your lungs and clear any phlegm. You will be given a device called a "Spirometer" to help you perform the exercises correctly. You will be taught how to use the device. You should practice the breathing exercises daily before your operation.

Preventing deep vein thrombosis

To prevent blood clotting in your legs you will be asked to wear special stockings and you will be given an injection on the day before surgery.

After your operation

After the operation you will be on a urinary catheter. You may have a tube from the surgery site or a nasal tube which will only be put if found necessary and will be removed at the earliest. You will also have continuous infusion of pain medication through an epidural catheter on the back.

Pain relief

It is important that your pain is controlled after your operation so that you can:

- Breathe deeply
- Walk about

• Feel relaxed
• Sleep

Apart from the continuous infusion of pain medication you will be given periodic injections for pain relief. You will be asked about your pain as part of your regular observations, but it is important that you tell those who are caring for you if you are in any pain at any other time.

Your pain relief is very important – if you have pain, you must tell someone or you may have difficulty deep breathing, coughing or moving about. Failure to do so may lead to lung complications and may lengthen your recovery.

Daily milestones

After the surgery there a certain daily milestones that you are expected to achieve.

Day of surgery

1. Immediately after surgery you will be on oxygen through a mask.
2. You will be allowed to take sips of water on the day after surgery once you are fully awake (6-8 hours after surgery).
3. You are expected to sit up in your bed for at least half an hour.
4. You are expected to do the breathing exercises on the spirometer at least ten times in an hour.
5. If you had a nasal tube it will be taken off.

Day 1 after surgery

1. You will be allowed to take clear fluids.
2. You are expected to ambulate from bed to chair and also walk with help for a duration of 30 minutes.(minimum)
3. You have to continue the breathing exercises.
4. Your epidural infusion will be discontinued and the epidural as well as urinary catheter will be removed.

Day 2 after surgery

1. You are allowed to have thicker fluids.
2. You are expected to walk for a minimum of half hour two times in the day.
3. You have to continue breathing exercises.
4. Your pain medications will be changed to tablets/suppositories.

Day 3 after surgery

1. You can have thick fluids and introduce some soft solid diet.
2. You are expected to walk for half hour two times in the day.(minimum)
3. Continue breathing exercises.

Day 4 onwards

You can continue near normal activities. You are allowed to take normal diet. You will be discharged in the subsequent days if your pain is under control, you are able to have solid foods, you are able to ambulate well and your doctor feels that you are fit to be discharged.

Do not stress about achieving all the above milestones. Each person responds differently. Your postoperative milestones may be altered from what is mentioned above, if your treating doctor feels so in your best interest.
If you develop any postoperative complication you will be treated for it as is applicable for all post-operative patients.

ERAS in Subtotal Gastrectomy

Id number

DEMOGRAPHIC FACTORS

PATIENT'S NAME:

AGE: completed years

GENDER: M / F

HOSPITAL NUMBER:

D.O.B:

ADDRESS:

TELEPHONE:

EMAIL ID:

DATE OF ADMISSION:

WEIGHT IN KG:
HEIGHT IN CM:
BMI:

DISEASE PARAMETERS

TISSUE DIAGNOSIS:

TOTAL DURATION OF SYMPTOMS:

SITE OF TUMOUR:

SIZE OF TUMOUR:

COMORBIDITIES: DURATION

1. DIABETES MELLITUS: Y/N
2. HYPERTENSION: Y/N
3. CARDIAC DISEASE: Y/N
4. RESPIRATORY DISEASE: Y/N
5. RENAL DISEASES: Y/N
6. OBESITY: Y/N
7. OTHERS:

SMOKER: Y/N DURATION:
ALCOHOLIC: Y/N DURATION:

Hemoglobin:

Id number

PRE-TREATMENT STAGING.

TUMOR- T0, Tis, T1, T2, T3, T4
NODES- NO NODES / LOCOREGIONAL/DISTANT
METASTASIS – M0, M1

NEOADJUVANT CHEMO OR RADIOTHERAPY (PRE-OP) : Y/N

INTRAOP

ASA STATUS: 1/2/3/4/5

DATE OF SURGERY:

TYPE OF ANASTOMOSIS:

1. HAND SEWN CONTINUOUS
2. HAND SEWN INTERRUPTED
3. STAPLED

– STAPLER SIZE___

COMPLICATIONS/COMMENTS:

DURATION OF SURGERY:

ESTIMATED BLOOD LOSS IN ML:
INTRA OP TRANSFUSION : Y/N IF YES NUMBER OF UNITS :
POST OPERATIVE TRANSFUSION: Y/N IF YES NUMBER OF UNITS :
INTRAOPERATIVE CRYSTALLOID USED:

POSTOPERATIVE

HISTOPATHOLOGY REPORT:
POST OPERATIVE TNM STAGING:

TUMOR- T0, Tis, T1, T2, T3, T4
NODES- NO NODES / LOCOREGIONAL/DISTANT
METASTASIS – M0, M1

SITE OF TUMOUR:

OUTCOME PARAMETERS

DURATION OF HOSPITAL STAY: POD___
RE ADMISSION: Y/N IF YES, PLEASE SPECIFY REASON:

DATE OF STARTING NORMAL DIET:

DAY OF PASSAGE OF FLATUS:

DAY OF PASSAGE OF FAECES:

ERAS in Subtotal Gastrectomy

Id number

DATE OF DISCHARGE:

CLAVIEN-DINDO CLASSIFICATION OF COMPLICATIONS:

REOPERATION REQUIRED: Y/N.
DETAILS OF REOPERATION:

POST OP COMPLICATION

Clavien Dindo Classification.

Grades	**Definition**
Grade I:	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
Grade II:	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Grade III:	Requiring surgical, endoscopic or radiological intervention
Grade III-a:	Intervention not under general anesthesia
Grade III-b:	Intervention under general anesthesia
Grade IV:	Life-threatening complication (including CNS complications: brain haemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischaemic attacks) requiring IC/ICU management.
Grade IV-a:	Single organ dysfunction (including dialysis)
Grade IV-b:	Multi-organ dysfunction
Grade V:	Death of a patient
Suffix 'd':	If the patients suffers from a complication at the time of discharge, the suffix “d” (for ‘disability’) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

ERAS PROTOCOLS FOLLOWED

PREOPERATIVE	COMPLIANCE
• Counselling the patient and relatives regarding the disease, proposed surgery, protocol for ERAS and its advantages. (handout) • Provide the patients preoperative oral nutritional supplement. • Counselling patients to quit smoking and alcohol use. • Training patients to do incentive spirometry. • First dose of DVT prophylaxis.	
INTRAOPERATIVE	

• Anaesthesia – Endotracheal intubation and GA + Thoracic Epidural. (other modes of regional analgesia if needed) • Antibiotic prophylaxis at induction of anaesthesia. • Avoid hypothermia during surgery • Intra OP fluid restriction. (in conjunction with anaesthetist) • Avoid NG tube and drains whenever possible (unless specifically deemed necessary)	
POSTOPERATIVE	
• Perioperative oxygen therapy – till 6hours post OP • Incentive spirometer once the patient is awake. • Analgesia – thoracic epidural analgesia + intravenous paracetamol till 48 hours. Add on non opioid analgesics if pain scores more than 5 on a visual analogue score. • Diet – start on few sips of clear fluids on day of surgery followed by liquid diet from day 2 and soft solid diet from day 3 • Removal of NG tube (if present) – within 24 hours • Removal of Urinary catheter – within 48 hours (along with epidural) • Ambulation – mobilize to chair on day of surgery, start progressive ambulation from day 2. • Continue DVT prophylaxis.	
Type of surgery and the limit of resection – standardised	

Reason If any protocol not followed

Patient No : Name: Hospital No:

ERAS (ENHANCED RECOVERY AFTER SURGERY) FOLLOWING SUBTOTAL GASTRECTOMY

Protocol for study patients

Preoperative	**Intraoperative**
1. Counselling regarding procedure. 2. Teach incentive spirometry. 3. DVT prophylaxis with heparin / clexane.	1. Epidural analgesia. 2. Minimum intraop fluids.

Please record whether following protocol was followed and give reason if unable to comply.

Postoperative orders		Reasons if answer is No
Oxygen 4L/min by mask for 6 hours.	**Y / N**	
Sips of water once fully awake.	**Y / N**	
Incentive spirometer once fully awake	**Y / N**	
DVT prophylaxis.	**Y / N**	
Any need for analgesia other than epidural and paracetamol	**Y / N**	

Post op day 1

NG tube if present – to be removed within 24 hours.	**Y / N**	
Patient made to sit up for minimum half hour in bed.	**Y / N**	

Post op day 2

Urinary catheter removed within 48 hours.	**Y / N**	1. Well-functioning epidural analgesia 2. If others specify -
Increase oral sips	**Y / N**	
Ambulation from bed to chair and starting to walk by evening.	**Y / N**	

Patient No : Name: Hospital No:

Post op day 3 Reasons if answer is No

Remove epidural	**Y / N**	1. Well-functioning epidural analgesia 2. If others specify –
Ambulation minimum twice a day	**Y / N**	
Clear Liquids orally	**Y / N**	

Post op day 4

Liquids as tolerated	**Y / N**	
Progressive ambulation.	**Y / N**	

Post op day 5

Soft solid diet	**Y / N**	
Normal activity	**Y / N**	

Patient may be discharged if :

- Adequate oral diet without parenteral fluids
- Normal body temperature
- Pain is controlled with oral analgesics
- Mobilizing comfortably
- Normal gastrointestinal function (flatus and defecation)

Ready for discharge date: Actually discharged on:
Reason for delay:

Please record any other relevant postoperative events

sno	grp	age	sex	doa	dis	dod	dos	typ	dur	asa	res	op	flu	bld	trn	dia	htn	com	cou	hep	inc
1	1	57	2	24/09/2014	08/10/2014	08/10/2014	25/09/2014	1	24	1	TRUE	FALSE	2500	150	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
2	1	54	1	14/09/2014	07/10/2014	07/10/2014	16/09/2014	1	6	1	TRUE	FALSE	1500	500	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
3	1	62	1	10/09/2014	15/09/2014	16/09/2014	11/09/2014	1	2	2	FALSE	FALSE	9	9	FALSE	FALSE	TRUE	TRUE	TRUE	TRUE	TRUE
4	1	65	1	03/09/2014	08/09/2014	09/09/2014	04/09/2014	1	2	1	TRUE	FALSE	1000	50	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
5	1	64	1	13/08/2014	18/08/2014	19/08/2014	14/08/2014	1	12	2	FALSE	FALSE	3000	100	FALSE	FALSE	TRUE	FALSE	TRUE	TRUE	TRUE
6	1	36	2	20/04/2014	27/04/2014	27/04/2014	22/04/2014	1	24	2	TRUE	FALSE	1500	100	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
7	1	55	1	21/04/2014	27/04/2014	29/04/2014	22/04/2014	1	6	1	TRUE	FALSE	2000	300	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
8	1	41	2	23/04/2014	29/04/2014	30/04/2014	24/04/2014	1	24	2	TRUE	FALSE	1500	9	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
9	1	48	2	26/02/2014	31/05/2014	01/06/2014	27/05/2014	1	72	1	TRUE	FALSE	1500	9	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
10	1	65	1	11/06/2014	10/07/2014	12/07/2014	12/06/2014	1	6	2	TRUE	FALSE	1500	100	FALSE	FALSE	TRUE	FALSE	TRUE	TRUE	TRUE
11	1	27	2	22/06/2014	29/06/2014	29/06/2014	24/06/2014	1	1	1	TRUE	FALSE	1000	50	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
12	1	65	1	25/06/2014	01/07/2014	02/07/2014	26/06/2014	1	5	1	TRUE	FALSE	2000	200	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
13	1	54	1	23/07/2014	30/07/2014	31/07/2014	24/07/2014	1	6	1	FALSE	FALSE	1500	9	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
14	1	47	2	23/07/2014	31/07/2014	31/07/2014	24/07/2014	1	1	1	TRUE	FALSE	1500	75	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE	TRUE
15	1	78	1	04/08/2014	13/08/2014	13/08/2014	05/08/2014	1	24	2	TRUE	FALSE	2000	100	FALSE	FALSE	TRUE	FALSE	TRUE	TRUE	TRUE
16	1	54	1	15/12/2014	21/12/2014	22/12/2014	16/12/2014	1	12	1	TRUE	FALSE	1000	50	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
17	1	60	1	05/11/2014	15/11/2014	15/11/2014	06/11/2014	1	2	2	TRUE	FALSE	2500	150	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
18	1	65	1	06/10/2014	16/10/2014	17/10/2014	09/10/2014	1	3	1	TRUE	FALSE	2000	300	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
19	1	56	1	19/10/2014	26/10/2014	26/10/2014	21/10/2014	1	24	1	TRUE	FALSE	1500	50	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
20	1	48	1	22/10/2014	27/10/2014	28/10/2014	23/10/2014	1	3	2	TRUE	FALSE	1500	100	FALSE	TRUE	FALSE	FALSE	TRUE	TRUE	TRUE
21	1	52	1	22/10/2014	31/10/2014	01/11/2014	23/10/2014	1	24	1	TRUE	FALSE	3000	100	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
22	1	44	1	23/11/2014	29/11/2014	01/12/2014	25/11/2014	1	12	1	TRUE	FALSE	2000	50	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
23	1	39	1	30/11/2014	08/12/2014	08/12/2014	02/12/2014	1	4	1	TRUE	FALSE	2000	50	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
24	1	35	2	03/12/2014	24/12/2014	24/12/2014	04/12/2014	1	6	1	TRUE	FALSE	1500	100	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
25	1	45	1	15/12/2014	24/12/2014	25/12/2014	18/12/2014	1	1	2	TRUE	FALSE	2500	100	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE	TRUE
26	1	35	2	23/02/2015	15/03/2015	15/03/2015	24/02/2015	1	2	1	TRUE	FALSE	1500	150	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
27	1	52	2	12/11/2014	17/11/2014	18/11/2014	13/11/2014	1	4	1	TRUE	FALSE	2500	100	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
28	1	62	1	04/01/2015	17/01/2015	18/01/2015	06/01/2015	1	1	2	TRUE	FALSE	1500	150	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE	TRUE
29	1	46	2	07/01/2015	14/01/2015	15/01/2015	08/01/2015	1	4	1	TRUE	FALSE	2000	200	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
30	1	84	2	19/01/2015	25/01/2015	30/01/2015	20/01/2015	1	2	3	TRUE	FALSE	1000	50	FALSE	TRUE	TRUE	FALSE	TRUE	TRUE	TRUE
31	1	67	1	11/02/2015	19/02/2015	20/02/2015	12/02/2015	1	4	2	TRUE	FALSE	1500	200	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
32	1	44	1	18/02/2015	24/02/2015	24/02/2015	19/02/2015	1	4	1	TRUE	FALSE	9	9	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
33	1	57	1	25/03/2015	30/03/2015	01/04/2015	26/03/2015	1	24	2	TRUE	FALSE	1500	200	FALSE	FALSE	TRUE	FALSE	TRUE	TRUE	TRUE
34	1	57	2	01/04/2015	07/04/2015	07/04/2015	02/04/2015	1	8	1	FALSE	FALSE	9	9	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
35	1	57	2	02/03/2015	08/03/2015	08/03/2015	03/03/2015	1	7	2	FALSE	FALSE	1500	50	TRUE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
36	1	67	1	09/03/2015	22/03/2015	22/03/2015	10/03/2015	1	2	1	TRUE	FALSE	2000	100	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
37	1	60	1	09/03/2015	18/03/2015	18/03/2015	12/03/2015	1	4	1	TRUE	FALSE	1500	100	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
38	1	62	1	15/03/2015	23/03/2015	23/03/2015	17/03/2015	1	3	2	TRUE	FALSE	2000	200	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
39	1	52	1	15/03/2015	23/03/2015	24/03/2015	17/03/2015	1	2	1	TRUE	FALSE	1500	100	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
40	1	73	1	15/03/2015	23/03/2015	23/03/2015	17/03/2015	1	15	2	TRUE	FALSE	1500	200	FALSE	TRUE	FALSE	FALSE	TRUE	TRUE	TRUE
41	1	34	1	04/03/2015	11/03/2015	11/03/2015	06/03/2015	1	8	2	TRUE	FALSE	1500	150	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE	TRUE
42	1	65	2	07/05/2014	13/05/2014	13/05/2014	08/05/2014	1	12	1	FALSE	FALSE	1000	100	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
43	1	57	1	12/05/2014	19/05/2014	19/05/2014	13/05/2014	1	5	1	TRUE	FALSE	1500	300	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE
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